Manual on Expanded Program on Immunization

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Manual on Expanded Program on Immunization

DEPARTMENT OF SURVEILLANCE & DISEASE CONTROL

Expanded Program on Immunization

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Constructive suggestions for improving or updating this Manual would always be gratefully received.

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Acronyms

(A)AFB	(Alcohol)-acid-fast bacilli
AEFI	Acute events following immunization
AFP	Acute flaccid paralysis
ARI	Acute respiratory tract infections
ATS	Anti-tetanus serum (equine)
BCG	Bacille Calmette Guerin
CSF	Cerebrospinal fluid
DGHA	Directorate General of Health Affairs
DPT	Diphtheria, pertussis, tetanus
DSDC	Department of Surveillance & Disease Control
DT	Diphtheria, tetanus (child type)
DTaP	Diphtheria, tetanus, acellular pertussis
EHC	Extended health centre
EMRO	WHO Regional Office for the Eastern Mediterranean
EPI	Expanded Programme on Immunization
GBS	Gullian Barre' syndrome
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HC	Health centre
Hib	Haemophilus influenzae type b
HIV	Human immunodeficiency virus
ID	Intradermal route
IM	Intramuscular route
IPV	Injectable poliomyelitis vaccine (killed)
ISO	International standards organization
IU	International units
MCH	Maternal and child health
MMR	Measles, Mumps, & Rubella vaccine
MoD	Ministry of Defence
MoE	Ministry of Education
MoH	Ministry of Health
MOIC	Medical officer in-charge
MR	Measles, Rubella vaccine
NID	National Immunization Day (Polio campaign)
NWCCP	National women and child care plan
OPV	Oral poliomyelitis vaccine
PDO	Petroleum development organization
PHS	Public health section
ROP	Royal Oman police
RVS	Regional vaccine stores
SQU	Sultan Qaboos University
TIG	Tetanus immune Globulin (human)
Td	Tetanus-diphtheria [toxoid] adult type
TT	Tetanus toxoid
UNICEF	United Nations Children's Fund
V&B	Vaccine and Biologicals
VPD	Vaccine preventable diseases
VQ	Vaccine qualified (clinic)
VVM	Vaccine vial monitor
WHO	World Health Organization

Forward

EPI program was one of the first health programme launched in Oman. In the last 30 years, Oman has transformed from an isolated undeveloped country to a modern welfare state. The dramatic decreases in mortality rates and other positive indicators of health and well-being, in conjunction with other political and economic transformations are due to the dedication and commitment of the Sultanate's leader, H.M. Sultan Qaboos. One of the most significant features is the dramatic drop in the infant mortality rate from around 125 per 1000 live births in the 1970's to less than 16.2 per 1000 by the year 2001 and this can be attributed in part to the Expanded Programme on Immunization (EPI).

Childhood immunization was one of the components of health services in Oman in the 1970's. But it was not until 1981 that the EPI Programme was launched with the establishment of an office and recruitment of staff for the programme. A comprehensive childcare programme was launched nationally in 1987 and the child health card and child health register (MR2 register) was introduced. As a result, immunization coverage increased throughout the late 1980's and early 1990's and coverage of more than 95% has been maintained since the early-1990's for all the vaccines in the EPI schedule.

In the early 1990's there was a measles/rubella epidemic in which more than 3000 cases were reported. Most of those affected were children born before 1987 when immunization coverage was comparatively low. Due to this outbreak, a Measles-Rubella (MR) vaccination campaign was held to vaccinate all children between the ages of 15 months and 18 years. Subsequently, a second MR dose was introduced into the EPI schedule. The EPI programme has now initiated the Hepatitis B campaign targeting all children not covered by the EPI programme. By the end of the Year 2004, everyone under the age of 20 years would have been vaccinated against Hepatitis B. Thus, the EPI schedule has been revised and expanded several times over the past 20 years and now includes immunizations for 10 antigens; the latest was the introduction of the Hib vaccine this year.

This manual provides a comprehensive overview of the vaccines provided in the EPI programme, the immunization schedule, adverse-events-following-immunization, the vaccine cold chain, and EPI disease surveillance follow-up and reporting.

It is hoped through this revised Standard Operating Procedures Manual all staff of the Ministry of Health and sister institutions will feel responsible for sustaining the universal acceptance by the community that immunization is vital to the life, health and well-being of the children of this country and the resulting high immunization coverage.

Dr. Ali Jafer M. Suleiman
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Chapter

1

Introduction

1.1 Global Scenario

World Health Assembly in 1974 adopted a resolution and launched the Expanded Program on Immunisation (EPI). Since the 1980s, considerable progress in immunization worldwide has helped to decrease mortality in young children. As a result of immunization almost 3 million lives have been saved each year, and 750,000 children are saved from disability.

In 1999, the worldwide average vaccination coverage of children under five was 74%. One in every four children in the world remains without immunization against the six diseases initially covered by EPI (Measles, Polio, Pertussis, Diphtheria, Tetanus and tuberculosis)

Access to immunization varies greatly across the world. A child in a developing country is ten times more likely to die of a vaccine-preventable disease than a child from an industrialized one. In some countries, up to 70% of children do not receive the full set of vaccines; the lowest coverage is found in sub-Saharan Africa. In Africa as a whole, over 40% of children are not immunized against Measles, a major cause of infant mortality that kills one child every minute. WHO has been recommending vaccination against Hepatitis B since 1993, yet it kills approximately one million people each year.

Against this background, the World Health Assembly set the goal of immunising 80% of the world's children by the end of 1990. This goal was achieved by a majority of countries in the developing world, and almost all countries ended in 1990 with immunisation levels close to the 80% target (75% for sub-Saharan Africa). Following a drop-off in 1991 and three subsequent years of flat growth, worldwide immunisation of children is now increasing again, according to the newly released figures from the World Health Organisation (WHO).

1.2 Progress of EPI in Oman

EPI in Oman was launched in 1981 with a substantial progress in the last two decades. Reviews of the programme conducted by international agencies in 1983, 1987, 1989, 1993 and 2000 (Polio) documented a well designed and implemented program with increasing rates of vaccination coverage.

Immunization coverage levels have increased substantially from 10% in 1981 to over 95% in 1995. The near 100% coverage has been maintained till 2001, resulting in corresponding impact on Vaccine Preventable Diseases (VPD) in Oman as evident in the Table 1.

Table-1:
Incidence of EPI Target diseases in Oman

Diseases	1981	1990	1995	2000
Poliomyelitis	43	0	0	0
Neonatal Tetanus	10	0	1	0
Tetanus	36	3	7	0
Measles	40,679	1,262	68	9
Diphtheria	10	0	0	0
Pertussis	2,236	49	108	205
Rubella	NA	27	46	3
Mumps	NA	11,375	14,574	10,443
Hepatitis B	NA	NA	622	49

(NA – Not Available)

The marked achievement in immunization coverage has resulted from an expansion of EPI at to the grass root level. EPI has been integrated into the Primary Health Care services provided by the Ministry of Health. Other sister health organizations viz. Sultan Qaboos University (SQU) hospital and health services provided by the Petroleum Development Organization (PDO), Armed Forces, Royal Oman Police (ROP), Palace clinics as well as the private health establishments have also contributed to the programme's remarkable success in Oman.

The cold chain monitoring and supervision has also contributed to the achievements. Similarly the unique system of child health card and institution based child health register was established at the outset. Every child was born was assigned a unique identifier, known popularly as the MR2 number. The concept of catchment area of a health institution was evolved. A child could receive immunization anywhere in the country but his records would be maintained at its parent health institution. Every visit by the mother to the health institution was considered as an opportunity to check the immunization status of the child. Thus this system proved to be an effective tool for defaulter retrieval. More coverage was achieved by reliance on the static EPI units in the health institutions rather than a house-to-house visit by the outreach teams in the past. The success of the programme is none the less also due to the active support of the community.

1.3 The Milestones of EPI in Oman

Expanded Programme on Immunization formally launched in Oman in 1981

Early 70s to 1989:	BCG, OPV, DPT, & Measles: standard regime (primary & boosters) Booster doses of DPT, DT & OPV integrated into School Health Programme
1989	Introduction of birth dose of OPV
1990	Introduction of dose of OPV at 40 days (*Al Arbayeen dose*)
August 1990	Introduction of Hepatitis B vaccine (0, 3 & 7 months)
March 1994	Introduction of Rubella & second dose of Measles at 15 months as MR
August 1995	Introduction of Vitamin 'A' supplementation as part of EPI along with Measles & MR vaccine (9 & 15 months)
January 1996	New policy on the use of opened vials in subsequent immunisations
	Introduction of a national surveillance system for monitoring Adverse Events Following Immunisation (AEFI)
September 1997	Discontinuation of policy of BCG re-vaccination in school
October 1997	MR at 15 months replaced by MMR
January 1998	DPT rescheduled at 1 ½, 3 & 5 months, DPT & OPV boosters at 15 & 19 months respectively
June 1998	Vaccine Vial Monitor (VVM) introduced
June 1999	Discontinuation of policy of BCG re-vaccination at 3 months
February 2001	Introduction of Rubella vaccine for postpartum mothers
October 2001	Introduction of Hib vaccine
	Measles & MMR rescheduled at 12 & 18 months respectively
	DPT & OPV Booster at 18 months
	Vitamin 'A' supplementation at 7 & 12 months
	Introduction of IPV for immunocompromised & their contacts

National Immunization Campaigns:

March 1994	Catch-up campaign with MR vaccine (Target: 15 m to 18 yrs)
1995 to 1999 (5)	Polio, National Immunization Days (NIDs) (Target: < 5 yrs)
2001 to 2004	Hepatitis B Catch-up school campaign
Future Plans	Introduction of combined vaccine as Tetra/Penta (DT_aP/Hib/Hep-B)
	Introduction of Hepatitis A vaccine
	Introduction of Auto-Disable (AD) syringes

1.4 Immunization Policy

Ministerial Decree No. 127/92 and Article 14 of Royal Decree No. 73/92 act as background legislation documents on EPI policy in Oman.

It is the Policy of the Ministry of Health:

- To immunize **ALL** children under one year against the 10 vaccine preventable childhood diseases (primary immunization & boosters) and also to immunize all women in child bearing age with Tetanus Toxoid in order to eliminate Neo-Natal Tetanus.

  All these vaccines would be offered at all the MoH institutions, sister health organizations and vaccine qualified private clinics without incurring any cost to the beneficiaries.

  *(**Note:** The 10 vaccine preventable diseases are Tuberculosis, Diphtheria, Pertussis, Tetanus, Poliomyelitis, Measles, Hepatitis B, Rubella, Mumps & Haemophilus influenzae type b).*

- To offer specified **boosters** to the children under the school health programme.
- To use **every contact** of a child, mother and females in child bearing age with the health delivery system as an **opportunity** to check the immunization status.
- To strive to sustain a **universal acceptance** by the community that immunization is vital to the life, health and well being of the children.
- To strive to make **ALL** MoH and sister institution employees **feel responsible** for increasing and sustaining the immunization coverage in the area in which they work so as to reach near 100% coverage.
- To offer **Vitamin 'A' supplementation** of 100,000 IU along with measles dose at 12 months and 200,000 IU with MMR dose at 18 months.
- To maintain the immunization **records** in the…
  - **Child Health Card, MR-224 (Boys/Girls):** The card acts as the child's immunisation, health, and developmental record for the first 6 years of life.
  - **Child Health Register, MR-374:** The health institution based child health register acts as a comprehensive record of information related to child health.
- **EPI Quality Assurance Policy:**
  - The EPI is committed to provide services fulfilling following quality dimensions: accessibility, equity, continuity, safety, effectiveness and efficiency.
  - Establishing an ongoing supervisory and auditing system
  - Continually improving the quality of EPI services.

1.5 Immunization Strategy

Department of Surveillance & Disease Control, Directorate General of Health Affairs, MoH is the apex body at the national level responsible for formulating policies, planning, organisation, supervision and evaluation of the EPI programme.

The implementations of the EPI policies are carried out by a combination of the static units and the out-reach teams. However, the major emphasis in EPI service delivery is through the static units located within the health institutions.

1.5.1 Static Immunisation Units

EPI sections of all hospitals/health centres and extended health centres, designated public health sections of Ministry of Health, other non-MoH sister institutions (e.g. ROP, MoD, PDO, Palace clinic, SQU Hospital and Internal Security Services etc.) as well as vaccine qualified private clinics.

1.5.2 Outreach Immunisation

The designated health staff would conduct specified immunization tasks outside the health institutions e.g. defaulter retrieval, special immunization campaigns in schools, community or in remote and/or inaccessible areas whenever such needs arise.

1.5.3 Supervision & Auditing

The regional headquarters (provincial) are responsible for supervision and auditing of EPI in their respective regions. One EPI focal point has been trained by year 2000 in each of the administrative regions for routine monitoring of the EPI. The epidemiologist or the designated focal point of communicable diseases in the Directorate would provide technical assistance as well as supervise various activities related to EPI.

1.5.4 School health Programme

The nursing staff working under the school health programme would be responsible to conduct the scheduled immunizations. The records would be maintained in the appropriate documents.

1.6 Objectives & Service Targets

1.6.1 Immunisation Targets

- To sustain and consolidate a level of near 100% immunisation coverage of all infants for all the ten antigens against the EPI target diseases.
- To maintain a level of near 100% immunisation coverage with 2 doses or more of TT and Rubella vaccine for women of child-bearing age with an aim to sustain the elimination of Neo-Natal Tetanus and Congenital Rubella Syndrome (CRS).
- To coordinate with the Department of School Health to maintain full coverage of boosters included in the school immunization programme.

1.6.2 Disease Reduction Targets

- To **eliminate neonatal tetanus** and to sustain elimination thereafter.
- To sustain the polio free status (last case in 1993) till the ultimate goal of global **Poliomyelitis eradication** by the year 2005.
- To sustain **Measles elimination** with an ultimate goal of regional measles elimination in WHO-EMRO by 2010.
- To minimize the outbreaks of **Whooping cough** and to reduce its incidence to a level where it is no more a public health problem.
- Maintenance of **'zero'** status for Diphtheria.
- Reduction in the prevalence of **Hepatitis B** chronic carrier status in the population to low level (< 2%).
- Elimination of **Rubella & CRS** by 2005.

Chapter

2

Immunization Schedule

2.1 The EPI Schedule

Since the introduction of EPI in Oman the schedule was changed on various occasions based either on the evidence of the changing incidence of vaccine preventable diseases or on the recommendations of WHO.

2.1.1 The rationale for changes in EPI Schedule:

- **OPV:** The birth dose and *Al Arbayeen* (Day 40) dose was added to the earlier 3 dose schedule due to the outbreak of poliomyelitis in Oman in 1988/89. Thus currently five dose schedule of OPV is being followed for the primary immunization.
- **Measles/Rubella:** Second dose of Measles was added in 1994 along with Rubella (as MR vaccine) at 15 months after a mass catch-up campaign in the same year. The Measles vaccine was rescheduled to 12 and 18 months recently based on the specific recommendations by WHO for countries in the phase of measles elimination.
- **Vitamin 'A' supplementation:** Two doses of Vitamin 'A' (100,000 at 7 months and 200,000 at 12 months) are being offered based on the evidence of sub-clinical Vitamin 'A' deficiency amongst the children.
- **Hepatitis B:** Hepatitis B vaccine was added in August 1990 due to the concerns about the moderate endemicity of the disease in Oman and with the purpose of reducing its burden.
- **Pertussis:** During an outbreak in one of the regions of Oman in 1997, high incidence of cases in the children under 3 months of age was observed. Hence, the three doses of DPT were rescheduled at 1½, 3 and 5 months form January 1998.
- **Mumps:** The MR vaccine was replaced by MMR from October 1997.
- **Haemophilus influenzae type b:** Following the estimation of disease burden of Haemophilus influenzae type b (year 2000) the Hib vaccine was introduced

from October 2001in EPI on the basis of the findings of its cost-effectiveness.

2.1.2 **School Immunizations:** The second dose of BCG was omitted at school entry as recommended by WHO. Similarly DT booster was replaced by Td (adult formulation).

Table 2
The current EPI Schedule (Last revision in October 2001)

FIRST YEAR OF LIFE	
Due Age	**Vaccine (dose order)**
At Birth	BCG (1st dose) OPV (Birth) HBV (1st dose)
6 weeks	OPV 40 (Al Arbayeen dose) DPT (1st dose) HBV (2nd dose)
3 months	OPV (1st dose) DPT (2nd dose) Hib (1st dose)
5 months	OPV (2nd dose) DPT (3rd dose) Hib (2nd dose)
7 months	OPV (3rd dose) HBV (3rd dose) Hib (3rd dose) Vitamin A (100,000 IU)
12 months	Measles (1st dose) Vitamin A (200,000 IU)
SECOND YEAR OF LIFE	
18 months	MMR (Measles 2nd dose) DPT Booster OPV Booster

2.2 Contraindications to Vaccination

Given the success of reduction in the incidence of the vaccine-preventable diseases in the Sultanate of Oman, and the consequent decline in levels of avoidable sickness, disability and death, it is important that every opportunity should be taken to immunize the target population in order to sustain the gains made so far.

General contra-indications include prior allergic reactions to the same or related vaccine. However it's not an absolute contraindication and the decision should be taken on case-to-case basis.

What conditions should NOT be taken as Contra-indications?

Mild or Moderately ill children (unless they fall under any of the Specific Contra-indications below) should be immunized in order to increase individual and community protection. Malnutrition, low grade fever, mild ARI or Diarrhoea and other minor illnesses are **NOT** contra-indications for vaccination. **The general rule is to immunise all children who are not sick enough to be hospitalised.**

Table 2:
Specific Contraindications to Vaccines

Vaccines	Specific Contra-indications
BCG	Clinical Symptomatic HIV infection or known immunodeficiency
DPT	*Any past history of seizures, other than febrile convulsions, (especially if these occurred after a previous dose of DPT)
OPV	Immunocompromised patients
Hib	**None**
Measles/MMR	**None****
TT	**None**
DT	**None**
Hepatitis-B	**None**

** In these children DPT should be deferred until evaluated by a Neurologist & progressive encephalopathy is ruled out.*
*** In severely symptomatic case, do not administer.*

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2.3 Immunization Policies for specific situations

- BCG, OPV and HBV must be given to all newborns, regardless of birth weight, provided the baby is well enough to be discharged from hospital. This includes premature and low birth weight babies.

  The rule of thumb is *"if the baby is well enough to be discharged from hospital then he/she is well enough to receive BCG, OPV and HBV prior to discharge".*

- Infants born to mothers who are sputum positive (for AFB) should be given primary prophylaxis with INH 5 mg/Kg body weight for a minimum period of 3 months and then vaccinated with BCG, **if tuberculin negative at 3 months** (not at birth as in

normal infants). If tuberculin positive then treat for 6 months in all **(for details refer to TB Manual 3rd edition 1998).**

- **Hepatitis B vaccination:** The schedule for Hepatitis B vaccination is initiated soon after birth in the present EPI schedule to prevent perinatal transmission. Mothers are NOT routinely screened for Hepatitis B surface antigen (HBsAg) during antenatal period; hence it is vital that the newborn receives the first birth dose of Hepatitis B vaccine **within 12 hours** after delivery. This also applies to sick and low birth weight babies. The above time frame is required to be followed strictly to reduce the risk of perinatal transmission.
- **Booster Dose of DPT vaccination:** In the EPI schedule, a booster dose of DPT is given at 18 months of age i.e. 1 year after the 3rd dose of DPT. It is clarified that the interval between the 3rd dose of DPT and booster dose could vary from 6 to 12 months (minimum interval is 6 months). Hence, children should be given the booster dose at 18 months of age, even if their primary schedule is delayed provided the minimum interval is respected.
- **Minimum interval** between doses should be at least **4 weeks** for OPV, Measles, Hib and DPT vaccines.
- **The recommended course** of each vaccine must be completed as scheduled. However in actual practice children may sometimes present for immunisation later than the exact intervals and times specified. In such instances, the child must be given the missed doses immediately irrespective of the gap between doses. **The immunisation series need NOT be re-started but must be continued.** Few examples are cited below:
    - A child who, on screening, is found to have had DPT/OPV first dose 6 or may be 12 months ago. This child should be given DPT/OPV second dose and **any other vaccine** for which he/she is due or overdue. The series should then be continued according to the minimum time interval.
    - A child is detected as a defaulter at 18 months with no measles at 12 months. It would therefore be ideal to give MMR vaccine to protect the child with 3 antigens and advise the mother to bring the child for measles vaccine after one month.
    - A woman who, on screening, is found to have had TT first dose one year previously should be given the second dose without restarting the series. *There is "NO" maximum interval between TT doses. Only minimum intervals between doses should be adhered to.*
- Every attempt must be made to immunise children on time i.e. as per the national immunisation EPI schedule. Any delay in completing the schedule exposes that child and all others in the community who are not fully immunised to precisely those risks of mortality and morbidity from the target diseases that immunisation is designed to avoid. *Therefore the note above about what to do in the case of an interrupted series should NOT be interpreted as an excuse to delay the subsequent doses.*
- **Administration of Tetanus Immune Globulin (TIG) to newborn:** TIG must be administered only to babies born outside the hospital and;

- Seen within 10 days of delivery
- Born to mother who does not have at least 2 documented doses of Tetanus Toxoid.
- Born to a mother who has not received prescribed TT schedule or born beyond the duration of protection (refer to table 3).
- Dose of TIG is 250 IU

Table 3:
Tetanus toxoid doses & duration of Immunity

Dose[1]	Minimum Interval[2]	Percent protected[4]	Duration of protection[5]
TT1	-	-	-
TT2	4 weeks	80 (60-90)	3 years
TT3	6 months[3]	95	5 years
TT4	1 year[3]	99	10 years
TT5	1 year[3]	99	life long

1. For practical purposes:
   - There are "NO" contraindications to the administration of tetanus toxoid
   - The risk of adverse reactions is negligible
   - Only well documented immunizations should be counted. If in doubt, give an extra dose.
2. There is "NO" maximum interval between doses
3. If the previous dose of tetanus toxoid was given during a pregnancy, this dose could coincide with one of the immunization of the child.
4. Optimal protection of the infant can only be expected if the woman receives the vaccine at least two weeks before the delivery.
5. For practical purposes it is assumed that the antibody levels in the mother and the umbilical cord are approximately the same.

Source: WHO

- **HIV infection & immunisation:** WHO & UNICEF have established guidelines for the immunisation of children and women of childbearing age with EPI recommended vaccines. It is recommended that individuals with known or suspected asymptomatic HIV infection receive all EPI vaccines as early in life as possible according to the national recommended schedule. **Individuals with symptomatic HIV infection can receive all EPI vaccines except OPV, BCG and Yellow Fever vaccines.**

Table 4
WHO/UNICEF recommendations for the Immunisation of HIV-infected children and women of childbearing age

Vaccine	HIV Infection		Optimal timing of immunisation
	Asymptomatic	Symptomatic	
BCG	Yes	No	Birth
DPT	Yes	Yes	6, 12 & 20 weeks
IPV	Yes	Yes	6, 12 & 20 weeks
Measles	Yes	Yes*	6 & 9 months
Hepatitis B	Yes	Yes	6, 10 &14 weeks
Yellow fever	Yes	No	-
Tetanus	Yes	Yes	5 doses

** In severely symptomatic case, do not administer*

2.4 School Immunization Schedule

Table 5
School Immunization Schedule

PRIMARY SCHOOL, LEVEL 1 (6 – 7 YEARS)	
Vaccine	**Schedule**
OPV Booster	One dose
DT Booster (one dose) OR **DT (2 doses)**	Give One dose to ALL children OR Give TWO DOSES at an interval of 4 to 6 weeks if NOT vaccinated previously, or if no documentary evidence available i.e. Immunization card.
PRIMARY SCHOOL, LEVEL 6 (12 – 13 YEARS)	
Vaccine	**Schedule**
Td Booster (one dose) (Adult) OR **Td (2 doses)**	For GIRLS and BOYS who have been fully immunized before with DPT and or DT Give a Booster dose (one dose) If NOT fully immunized as above or NO records available give **2 doses of Td** at an interval of 4 –6 weeks.

SECONDARY SCHOOL, LEVEL 2 (17 – 18 YEARS)	
Vaccine	**Schedule**
TT Booster (one dose) OR **TT (2 doses)**	If the student is fully immunized in class 6 Primary School give one dose. If NOT fully immunized as above or NO record available give 2 doses of TT at an interval of 4-6 weeks.
OPV Booster (one dose)	To be given to All students at this level

2.5 Tetanus Toxoid for Adults

Table 6
For Females in childbearing age (15 - 49 years)
& Adult males (18 years and above)

Vaccination Status	Action
▪ If immunized as per schedule in above and documentary evidence available.	▪ Give one Booster of TT every 10 years.
▪ If not immunized as per schedule above OR immunization status unknown	▪ Give 2 doses of TT at an interval of 4 to 6 weeks apart ▪ Give 3rd dose of TT with a minimum interval of 6 months after the 2nd dose. ▪ Give a 4th dose with a minimum interval of one year after the 3rd dose followed by a 5th dose after one year. ▪ Subsequently give one booster dose every ten years.

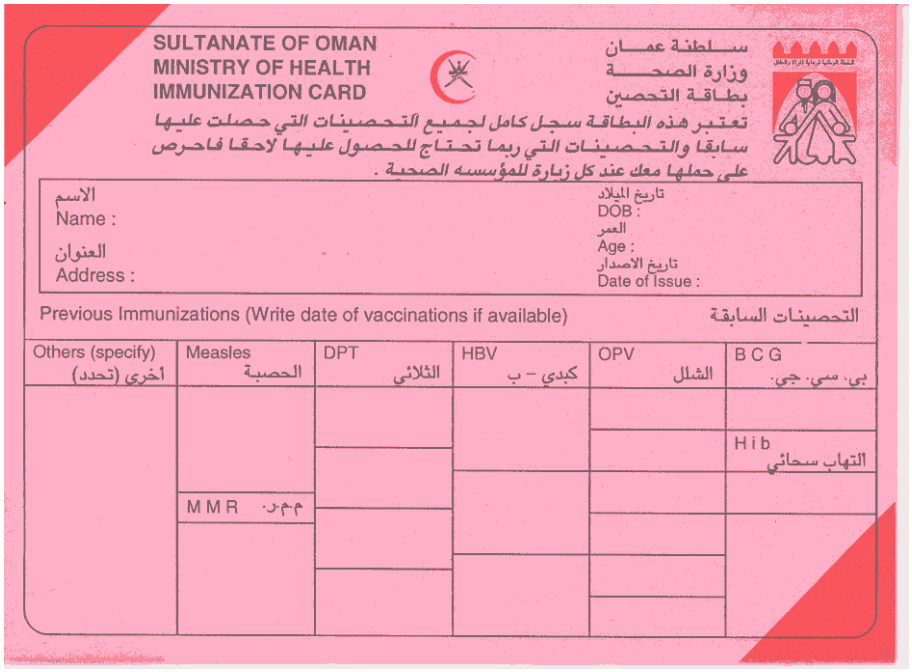
Notes:

- After 2 doses of TT (4 to 6 weeks apart) protective levels of anti-toxin are reached but decline over the next year.
- The 3rd dose of TT given (i.e. minimum 6 months after the 2nd dose) provides excellent immunity which lasts for about 5 years.
- Subsequent booster doses given restore protective immunity and should provide protection during child-bearing years.

- **All doses of TT given should be entered in the adult immunisation card (M-311) to act as a record of TT immunisation status for future reference. Sample of back side of the card is shown below.**
- **Apart from TT immunisation of pregnant and child-bearing age women every effort should be made to immunise males against tetanus as per prescribed schedule. Every contact with the health services should be taken as an opportunity to check for TT immunisation status and vaccine should be given, if due.**

The adult immunisation card (M – 311)

Front



SULTANATE OF OMAN
MINISTRY OF HEALTH
IMMUNIZATION CARD

سلطنة عمان
وزارة الصحة
بطاقة التحصين

تعتبر هذه البطاقة سجل كامل لجميع التحصينات التي حصلت عليها سابقا والتحصينات التي ربما تحتاج للحصول عليها لاحقا فاحرص على حملها معك عند كل زيارة للمؤسسه الصحية .

الاسم
Name :

العنوان
Address :

تاريخ الميلاد
DOB :
العمر
Age :
تاريخ الاصدار
Date of Issue :

Previous Immunizations (Write date of vaccinations if available) التحصينات السابقة

Others (specify) أخرى (تحدد)	Measles الحصبة	DPT الثلاثي	HBV كبدي - ب	OPV الشلل	B C G بي. سي. جي.
					Hib التهاب سحائي
	M M R م.م.ر.				

Back

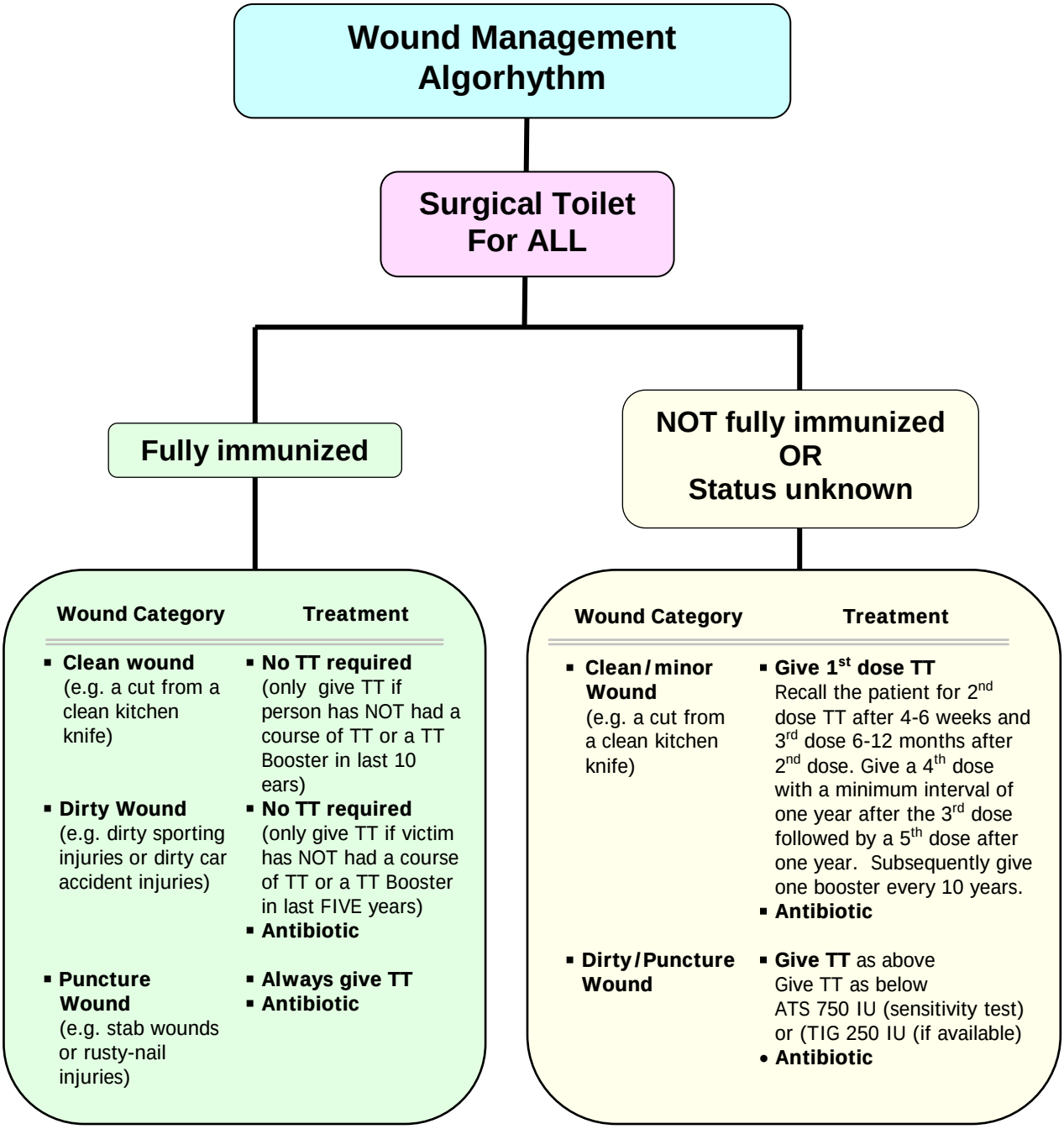
سجل تاريخ التحصين في أعلى كل مربع واسم المؤسسة في أسفله
Date of vaccination in top of box.
Name of institution in bottom of box.

سجل في المربعات التالية :
FILL IN :

المنشطة Booster	الجرعة الخامسة Dose 5	الجرعة الرابعة Dose 4	الجرعة الثالثة Dose 3	الجرعة الثانية Dose 2	الجرعة الأولى Dose 1	الطعم Vaccine :
						توكسيد التيتانوس TETANUS TOXOID
						الحمى الصفراء YELLOW FEVER
						الحصبة الألمانية RUBELLA
						التيتانوس/الدفتريا DT / Td

M - 311

2.6 Tetanus Toxoid in Wound Management


Wound Management Algorhythm
Surgical Toilet For ALL
Fully immunized
NOT fully immunized OR Status unknown
Wound Category
Treatment
Clean wound (e.g. a cut from a clean kitchen knife)
No TT required (only give TT if person has NOT had a course of TT or a TT Booster in last 10 ears)
Dirty Wound (e.g. dirty sporting injuries or dirty car accident injuries)
No TT required (only give TT if victim has NOT had a course of TT or a TT Booster in last FIVE years)
Antibiotic
Puncture Wound (e.g. stab wounds or rusty-nail injuries)
Always give TT
Antibiotic
Wound Category
Treatment
Clean/minor Wound (e.g. a cut from a clean kitchen knife)
Give 1st dose TT Recall the patient for 2nd dose TT after 4-6 weeks and 3rd dose 6-12 months after 2nd dose. Give a 4th dose with a minimum interval of one year after the 3rd dose followed by a 5th dose after one year. Subsequently give one booster every 10 years.
Antibiotic
Dirty/Puncture Wound
Give TT as above
Give TT as below
ATS 750 IU (sensitivity test) or (TIG 250 IU (if available)
Antibiotic

Note: In the event that a child under 7 years of age requires TT for wound management purposes, the child should be given DPT/DT rather than TT (unless there are any specific contraindications).

2.7 Route, Site and Dose of Vaccines

Table 7
Route & Site Vaccines

Vaccinees	Vaccine	#	Route	Site	Dose
Children under 2 years	BCG	1	ID	Left deltoid	0.05 ml***
	OPV	5 + 1*	Oral	Mouth	2 drops
	DPT	3 + 1*	IM	Left anterolateral thigh	0.5 ml
	Hib	3	IM	Left/right anterolateral thigh	0.5 ml
	Hep-B	3	IM	Right anterolateral thigh	0.5 ml
	Measles	1	IM	Right anterolateral thigh	0.5 ml
	MMR	1	IM	Right anterolateral thigh	0.5 ml
Children < 7 yr	DT	1**	IM	Left deltoid	0.5 ml
Children > 7 yr	Td/TT	1**	IM	Left deltoid	0.5 ml
Women: Pregnant & in child bearing age	TT	5 **	IM	Left deltoid	0.5 ml

* *Booster dose*
** *Give two doses 4 to 6 weeks apart if not vaccinated previously*
*** *Dose for children above one year is 0.1 ml.*

Note:
1. When two injections are required to be administered together use different limbs.
2. DPT conventionally should always be administered on the left anterolateral thigh.
3. Measles, MMR, Hep-B should preferably be administered on the right anterolateral thigh and Hib on either left or right.

Chapter

3

Adverse Events Following Immunization (AEFI)

3.1 Introduction

The goal of immunization is to protect the individual and the community from vaccine preventable diseases. Although modern vaccines are safe, no vaccine is entirely without risk. Some people experience reactions after immunization ranging from mild side effects to life-threatening, but rare, illnesses. In some cases, these reactions are caused by the vaccine; in others, they are caused by an error in the administration of the vaccine; and in yet others, there is no relationship.

To increase acceptance of immunization and to improve the quality of services, the surveillance of AEFI must become an integral part of the immunization programme. The benefits of immunizing against diseases like measles, neonatal tetanus, and polio far outweigh the risks of an incident caused by immunization. Monitoring events related temporally to immunization will enable us to reduce those risks even further. The formal AEFI surveillance system was launched in the country from January 1996.

3.1.1 Reporting of AEFI

An adverse event following immunization is a medical incident that takes place after an immunization and is believed to be caused by the immunization. Although people often think that a medical incident after an immunization must be caused by the immunization, many such incidents are coincidental. Another belief that vaccine is the most common cause of AEFI is also mistaken. Programme error, which can be prevented, is more often the cause.

3.1.2 AEFI to be included in surveillance

The immunization programme will monitor the following AEFI

- All cases of BCG lymphadenitis
- All injection site abscesses.

- All deaths that are thought by health workers, or the community, to be related to immunization.
- All cases requiring hospitalizations that are thought by health workers, or the community, to be related to immunization.
- Other severe or unusual medical incidents that are thought by health workers, or the public, to be related to immunization.

With respect to the third and fifth events, health workers may relate the event to immunization because it occurred within a month of an immunization, as its case definition indicates.

The above five categories of **AEFI** are sometimes called "trigger" events because their presence stimulates or triggers a response.

Investigation should begin as soon as possible, ideally within 24 hours of detection by a health worker, to identify any programmatic errors that might be present, to correct them before other people are exposed to the same error, and to show members of the community that their health and concerns are being taken seriously.

3.1.3 AEFI investigation

- In most cases, a preliminary investigation can be made by the health worker who detected the case, i.e. a nurse and paediatrician/physician in the hospital.
- Serious AEFIs or clusters should be investigated by the Regional Epidemiologist (wherever available) or the focal point of communicable diseases in the region in consultation with the Department of Surveillance & Disease Control.
- For the data to be collected for case or cluster investigation refer to AEFI investigation form in the annexure 1.
- The list definitions for monitoring AEFI are given in annexure 2.

3.1.4 AEFI Reporting

- After completing the AEFI report form (see annexure) a copy should be sent to the Director, DSDC on Fax No. 601832 and to the Department of Health Affairs of the region (Regional EPI focal point) within 24 hours of the event.
- Any death, severe AEFI or unusual medical incident must also be notified immediately during the same immunization session by phone or fax to the Director, DSDC and the Superintendent of. Health Affairs of the region.
- AEFI reporting form should be duly filled by the EPI nurse taking care that all relevant details are entered. The attending doctor should enter the clinical details, sign and dispatch.

Chapter

4

The Cold Chain

4.1 Introduction

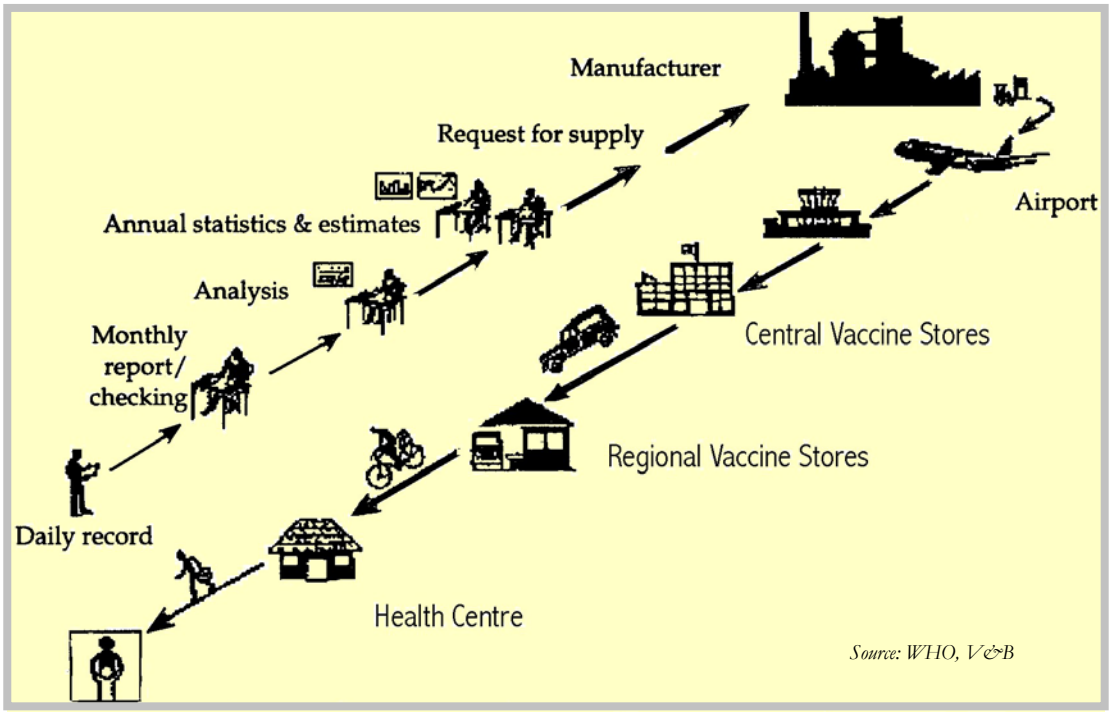
The Cold Chain is the system which ensures that vaccines remain potent from the from the moment of manufacture to the time of immunisation.

Vaccines deteriorate quickly when exposed to **HEAT** and/or **LIGHT**. If a child is immunised with a vaccine which has deteriorated, (i.e. a vaccine which has been rendered impotent), then it is as if that child had not been immunised at all.

The Cold Chain has three components:

- **People**: To organise and manage the vaccine distribution
- **Equipment**: To control and monitor the temperature of the vaccines.
- **Procedures:** The actions carried out to ensure that this equipment is correctly installed and maintained.

The Cold Chain reaches from the Manufacturer to the Recipient



4.2 Vaccine storage requirements

General Requirements: All vaccines must be stored at:

- **Correct Temperature:** The temperature requirements for vaccines at different levels are shown in Table 7.
- **In darkness:** this requirement will usually be satisfied if the vaccines are stored in the correct refrigeration equipment and only becomes an important independent requirement when vaccines are held ready for an immunisation session by Static Units or Outreach Teams. Hence vaccines must be kept in vaccine carriers when held ready for use and must **NOT** be exposed to light.

Table 8:
Temperature requirements at different levels

Unit	Vaccine	Temperature
Central & Regional Vaccine store	OPV, Measles, BCG	**Keep frozen at**... -20° to -30° C
	All other vaccines	+ 2° to + 8° C **Do NOT freeze**
Sub-Regional Vaccine store & EPI units	All vaccines including OPV, Measles, BCG All other vaccines	+ 2° to + 8° C **Do NOT freeze**

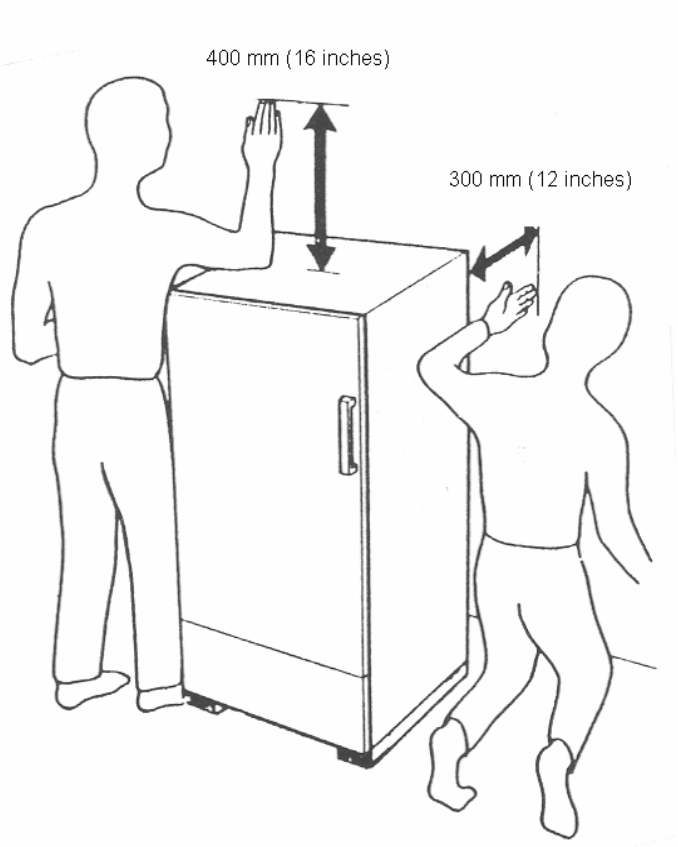
4.3 Vaccine Storage Equipment

4.3.1 Refrigerator

- **All Refrigerators (irrespective of the type of system):** must be placed in the coolest possible part of the Health Institution. They must **never** be placed in direct sunlight.
- Place the refrigerator close to an electric socket and in the coolest part of the building
- The room must be well ventilated and a good air circulation around the refrigerator is necessary. In very hot climates a fan should be used to blow air between the wall and the refrigerator.
- Keep the refrigerator in the shade and away from sources of heat of any kind.

Clearance from wall and roof must be as shown in the figure.

Fig. Correct Positioning of Refrigerator



Check that the plug fits into the electrical socket. If it does not, find a good plug that fits. Do not use adopters or take multiple connections from the same electrical socket.

Correct Internal Arrangement of the Refrigerator

The refrigerator must be organised internally according to the layout shown in the figure on page No. 34.

The following points are especially important:

Correct Arrangement of the ice packs: These help to stabilize the temperature in the refrigerator and are used when storing vaccines in a cold box.

Thermometer ON the vaccines: The thermometer should show the exact temperature of the vaccines and must therefore be placed on top of vaccine box (not on a different shelf)

Refrigerator routine checks & procedures

- **Correct Recording of Temperature:** In order to check that there has been no cold chain failure the temperature of the Refrigerator must be recorded on the Cold Chain refrigerator graph (form MR-247 on page 29) at the same time every day i.e. usually at the beginning and end of the immunization session. The graph should be displayed prominently on the refrigerator door. At the end of the month the graph should be filed. These records should be preserved for a period of two years.
- **Correct Periodic Checks:** reference should be made to the *User's Manual* supplied by the manufacturer with the equipment, for the frequency and type of checks that are to be carried out on each item of cold chain. For this purpose a copy of the appropriate *User's Manual* should always be accessible.

4.3.2 Deep freezer

Deep freezers have been supplied for;

- Storage of polio, measles and BCG vaccines at Central and Regional stores.
- Preparation of ice packs and storage of ice

Note: *DPT, DT, TT, HBV & Hib vaccines should* ***NEVER*** *be kept in deep freezers.*

4.3.3 Vaccine carriers

- Used for carrying small quantities of vaccines.
- Used for storing the vaccine vials during the immunisation sessions.
- Made of insulation material to preserve temperature.
- Vials of DPT, DT, TT, Hib and HBV should not be in direct contact with the frozen ice packs, especially during transportation and immunisation session. This can be ensured by packing these vials in cardboard boxes or plastic bags.
- Lid of the carrier should be shut tightly.

Note: Vaccine carrier should be used for vaccines only and not for any other purposes.

Fig. Vaccine Carriers: Geostyle & Thermos

Ice packs

- Used for lining the walls of cold boxes and vaccine carriers to keep them cold, and in refrigerator to help stabilise temperature at required level.
- They are flat plastic bottles filled with water/Gel.
- Prepared by keeping in deep freezer or freezer compartment of a compression refrigerator.
- Ice packs should stand with their edges in contact with the evaporator and not flat on one another, in the freezer compartment of refrigerator.
- Do not add salt to the water as it lowers the temperature to subzero temperature, which is not recommended for DPT, DT, TT, Hib and HBV.

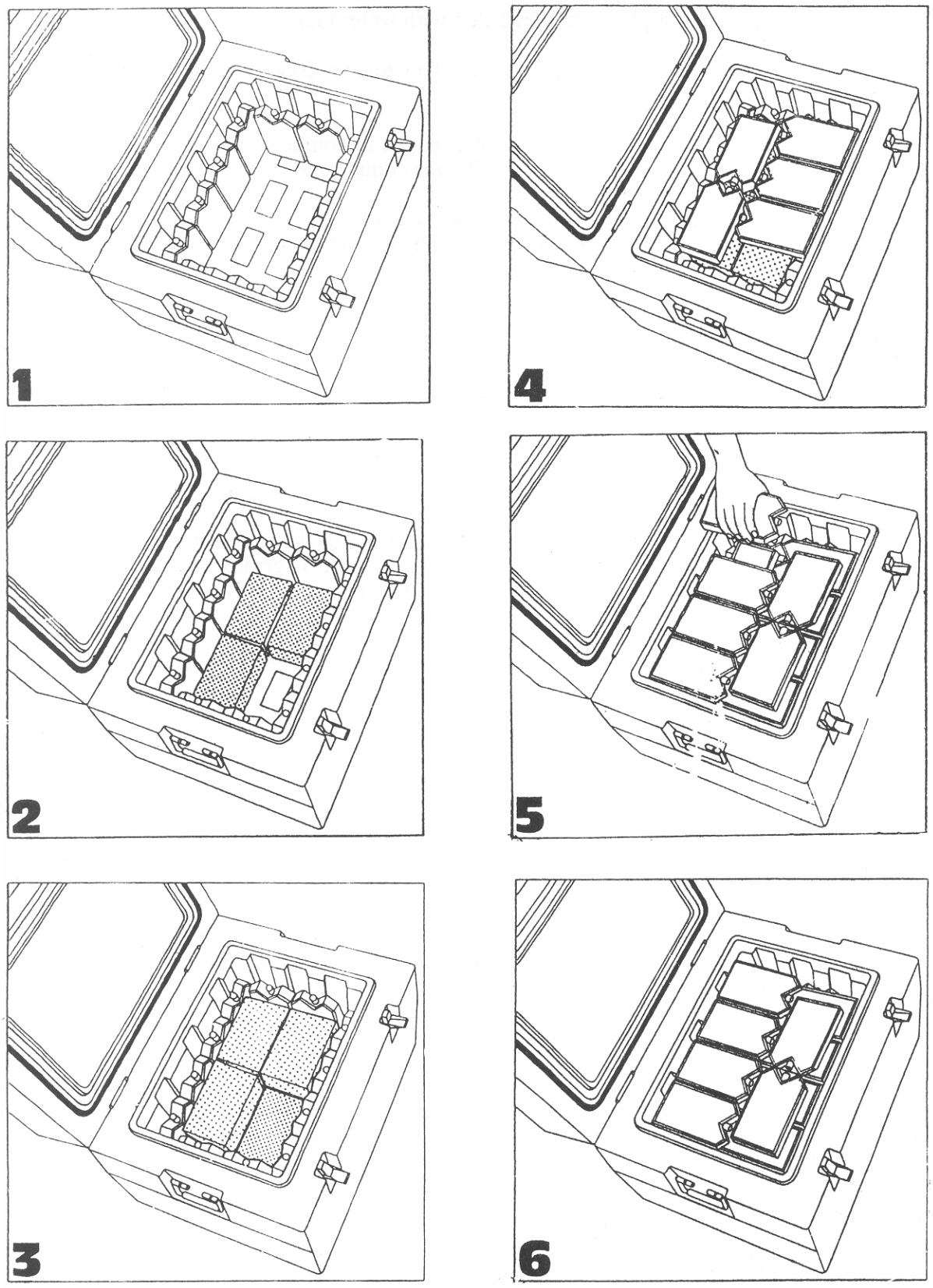
- While filling water in the ice pack do not fill it to the brim. Leave some air space to allow for ice expansion.
- Ice packs are also used as cold packs, to stabilise the temperature inside the refrigerator and to increase the time the refrigerator will maintain a safe temperature if electricity fails.
- Do not use leaking ice packs. Any damaged ice packs should be replaced.
- Use only the correct type & number of ice packs for each type of vaccine carrier & cold box. For Gio-style 7 ice packs, for Thermos style 4 ice packs and for RCW 25 22 ice packs required
- Do not over pack the freezer compartment. Ice packs should be loosely packed and placed obliquely to avoid cracking the freezer compartment.

4.3.4 Cold box (RCW25)

- To collect large quantities of vaccine for health centres/Regional store.
- Transport large quantities of vaccine by vehicle to Regional Vaccine stores.
- Carry vaccine for several days (maximum of 156 hours or 6 days without opening the box).
- Store vaccines when electricity fails.
- 22 ice packs are required (Type E5/04).

Fig. Cold Box: RCW 25

Fig.7 Method of arrangement of ice packs in the RCW 25



4.4 Cold Chain Monitoring Equipment

4.4.1 Vaccine cold chain monitor

- The cold chain monitor is a card which helps supervisors and health workers to check on the standard of vaccine handling in the cold chain. Monitor cards, which are packed with shipments of EPI vaccines from manufacturers, are also available for general use in the cold chain.
- To retain potency, all EPI vaccines must be kept at a temperature of 8°C or less at all points of the cold chain i.e. from the time the vaccines are manufactured, through their shipment to central warehouses, and to their distribution at regional, district and health centre levels.
- The monitor cards available in Oman in two languages...

  Arabic : Green card
  English : Yellow card

  Each monitor card has four windows for registering temperature changes. The instructions for interpreting the readings are printed on the monitor card (fig.).

How does the Monitor card works?

The monitor card has a heat-sensitive indicator in the form of a strip with 4 windows. This indicator operates at two different temperatures. To activate the card pull-out a small tab on the left hand side of the strip.

- When the strip is exposed to temperatures **above +10°C**, it functions as follows:
  - A blue colour begins to appear in the first window, marked 'A'. If the temperature then drops below +10°C the blue colour stops spreading to other windows.
  - Each time the strip is exposed to temperatures over +10°C the blue colour will spread further across the monitor from A to C. The colour change is irreversible. The colour may stop spreading, but will **NEVER RETURN** down the scale.
- When the window labelled "D" is exposed to temperatures **above +34° C**, it functions as follows:
  - It turns blue within 2 hours
  - Once the colour has changed to blue it will never change back to white.

What to do with the monitor card when it arrives?

There is usually one monitor card packed with each 3,000 doses of vaccine. When the vaccine arrives at each level (central, regional, sub-regional and health centre levels), the storekeeper should check the monitor card.

- To see if there is any blue colour on the strip. If there is no blue colour it means that this shipment of vaccine has never been exposed to temperatures above 10°C. If there is some blue colour, the storekeeper should inform his supervisor.
- The storekeeper should fill in the top part of the monitor card with the following information:
- The date of arrival of shipment.
- Name and location of the cold store
- To check if the letter of any window is entirely blue, the storekeeper should look at the strip and the disk and mark the index column. For example:
  - If there is no blue colour showing in any of the windows, fill in a dash.
  - If window A is entirely blue, write **"A"** in the index column
  - If window A & B are entirely blue, write **"A & B"**
  - If window A,B & C are entirely blue, write **"A & B & C"**
  - If window A & D are blue but the others are white, write **"A & D"**
  - If window A, B, C are white but D is blue, write **"D"**
  - If any window is **partly blue** do not place any mark in the index column

Importance of keeping the monitor card cool

The monitor cards should always be kept in the cold room or refrigerator, along with the vaccines with which they were originally packed. The card should be checked periodically for any colour changes by the vaccine store in-charge or the EPI staff nurse as applicable

Placement of monitor card when it leaves to other destinations

The storekeeper may have to send vaccines to several destinations at the same time. The ideal situation would be to have enough monitor cards for each destination. However, if he does not have enough monitor cards to do this, he could do either of the following:

- Pack all of the available monitor cards with the shipment to one destination. With the next despatch of vaccines he can then send the monitor card which is available at that time to another destination.

OR

- Place a monitor card with shipments going to destinations where the cold chain is suspected to be weak.

Before the storekeeper puts the monitor card with the vaccine he has to ensure to:

- Write the date on which the vaccine leaves the store, and

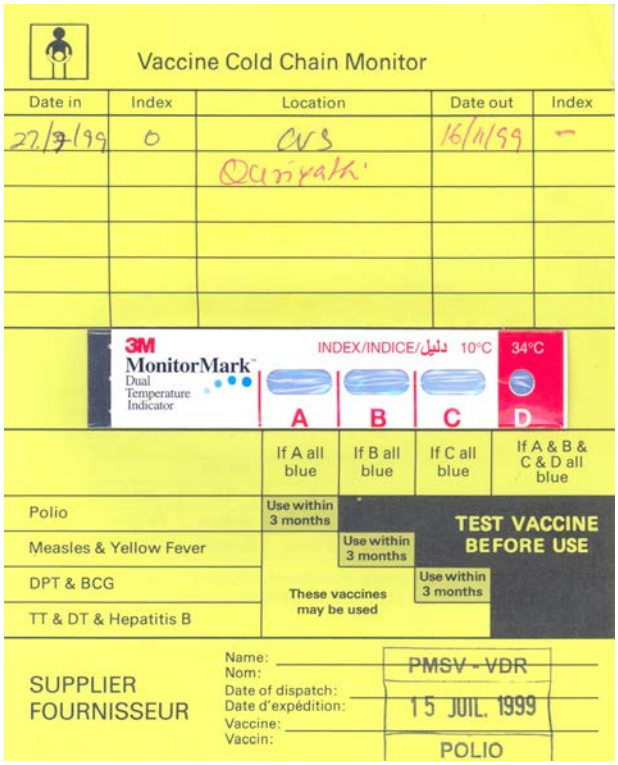
- Enter the index registered on the monitor.
- The health workers at regional, sub-regional & health centre levels should follow the same steps when they pack their cold boxes and vaccine carriers.

Actions to take when there is some blue colour on the card

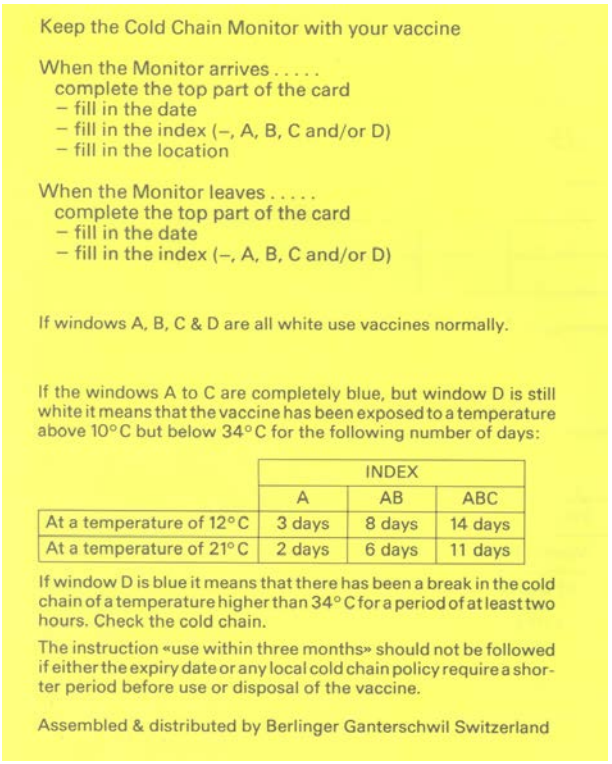
The RVS in-charge and EPI focal point at regional and Wilayat levels must routinely check the monitor cards and take appropriate actions when there is some blue colour showing in any of the cards.

Fig. Cold chain monitor card

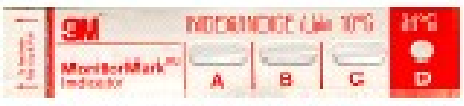
Front



Back


Keep the Cold Chain Monitor with your vaccine
When the Monitor arrives . . . . .
complete the top part of the card
– fill in the date
– fill in the index (–, A, B, C and/or D)
– fill in the location
When the Monitor leaves . . . . .
complete the top part of the card
– fill in the date
– fill in the index (–, A, B, C and/or D)
If windows A, B, C & D are all white use vaccines normally.
If the windows A to C are completely blue, but window D is still white it means that the vaccine has been exposed to a temperature above 10°C but below 34°C for the following number of days:
INDEX
A
AB
ABC
At a temperature of 12°C
3 days
8 days
14 days
At a temperature of 21°C
2 days
6 days
11 days
If window D is blue it means that there has been a break in the cold chain of a temperature higher than 34°C for a period of at least two hours. Check the cold chain.
The instruction «use within three months» should not be followed if either the expiry date or any local cold chain policy require a shorter period before use or disposal of the vaccine.
Assembled & distributed by Berlinger Ganterschwil Switzerland

Activation of the monitor card



1. Hold the tab at the left side of the monitor.

2. Fold tab over.

3. Fold tab back to break seal.

4. Pull tab straight out and remove.

4.4.2 Cold Chain Refrigerator and Freezer graph

The purpose of the graph is to monitor the refrigerator and freezer temperature and to identify any impending problem of cold chain failure. Ensure that at least one cold chain monitor & freeze watch is available in each refrigerator to monitor such failures.

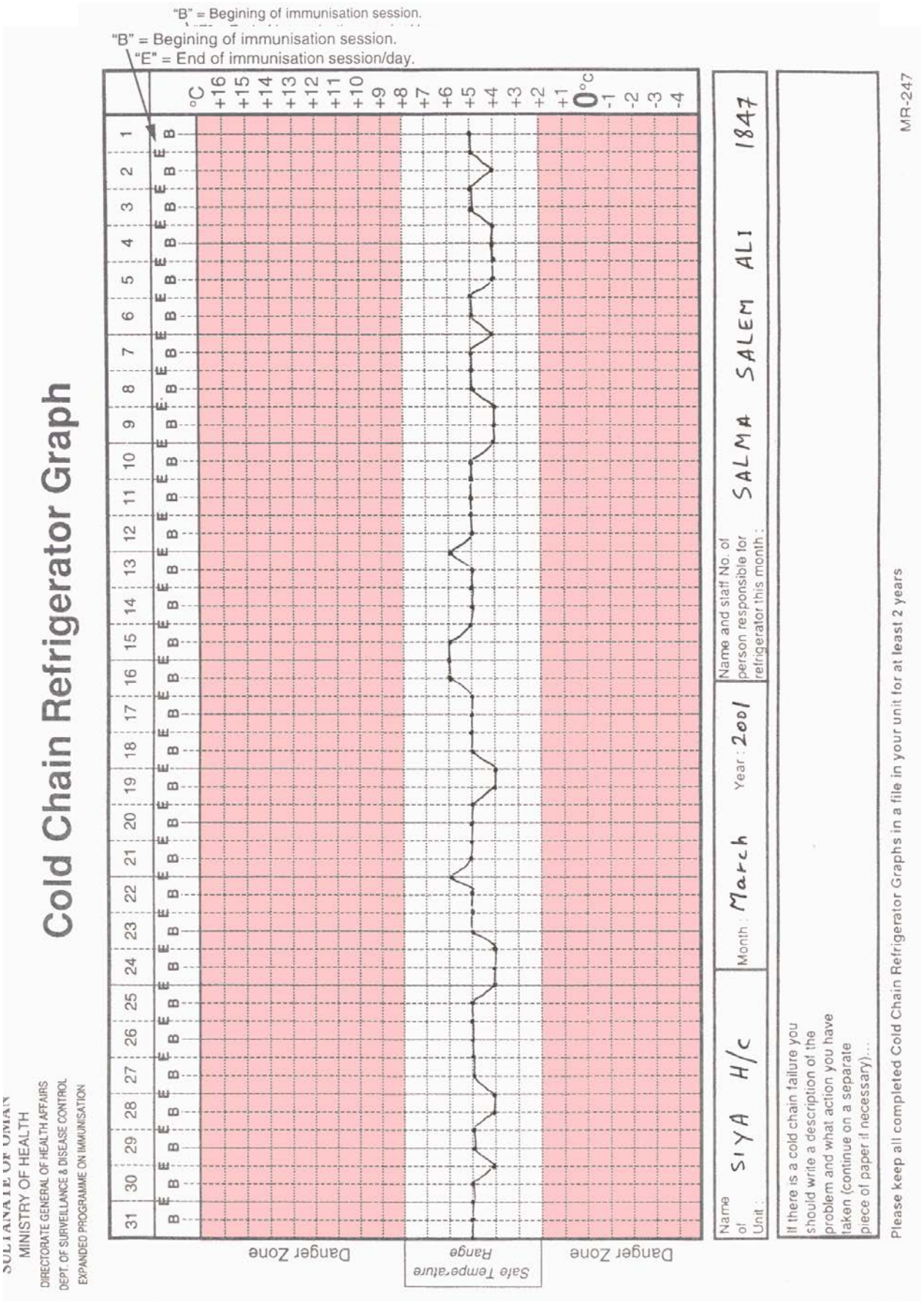
Scenarios and appropriate responses:

- If the temperature rises steadily over a few days it may probably mean that the compressor is failing. Immediately inform the MOIC to take appropriate action for repairs.
- If the temperature chart shows wide variations between the (B)egining of the session and the (E)nd of the session, you may be opening the refrigerator door too often. In this case minimize door opening and perhaps to increase the temperature stability increase the number of cold packs in the refrigerator.
- If when you monitor the temperature in the morning i.e. at the (B)egining of the immunisation session, you find the temperature say, 14°C, you have a cold chain failure.

In case of a Cold chain failure...

- √ Transfer the vaccines and cold chain monitors to a vaccine carrier or vaccine cold box.
- √ Contact your regional EPI focal point as well as the national EPI Supervisor in DSDC give them the facts and ask for guidance.
- √ Locate the cause of the problem. If it is simple e.g. the refrigerator was unplugged by the cleaning staff, correct the problem if you can.
- √ Replace the vaccines and cold chain monitors in the refrigerator after the problem has been solved and the temperature has returned to well within the safe range +2°C to +8°C.
- √ If there is a cold chain failure the person responsible for the refrigerator should write a brief description of the problem & what actions were undertaken. Forward a copy of this report to regional EPI focal point as well as to DSDC for information & record.

Fig. 10 – Cold Chain Refrigerator Graph


"B" = Begining of immunisation session.
"E" = End of immunisation session/day.
Cold Chain Refrigerator Graph
SULTANATE OF OMAN
MINISTRY OF HEALTH
DIRECTORATE GENERAL OF HEALTH AFFAIRS
DEPT. OF SURVEILLANCE & DISEASE CONTROL
EXPANDED PROGRAMME ON IMMUNISATION
°C +16 +15 +14 +13 +12 +11 +10 +9 +8 +7 +6 +5 +4 +3 +2 +1 0°C -1 -2 -3 -4
Danger Zone
Safe Temperature Range
Danger Zone
Name of Unit : SIYA H/c
Month : March
Year : 2001
Name and staff No. of person responsible for refrigerator this month : SALMA SALEM ALI 1847
If there is a cold chain failure you should write a description of the problem and what action you have taken (continue on a separate piece of paper if necessary)...
Please keep all completed Cold Chain Refrigerator Graphs in a file in your unit for at least 2 years
MR-247

4.4.3 Freeze watch

Freeze watch is an irreversible temperature indicator, to show if a package of vaccines was exposed to freezing temperature. The colour changes from white or blue colour if exposed to temperature, below 0°C (blue) for more than 1 hour. This warns the recipient that the vaccine was probably frozen.

The vaccines like DPT, TT, DT, Td, Hib and HBV if frozen loose their potency.

Fig. 12 Freeze Watch

3M Freeze Watch™
Made in U.S.A. 3M, St. Paul MN 55144-1000
LOT 2005-04 AC
9805FW (0°C/32°F)
Dark stained paper = Activated
3M Freeze Watch™
Made in U.S.A. 3M, St. Paul MN 55144-1000
LOT 2005-04 AC
9805FW (0°C/32°F)
Dark stained paper = Activated

The indicator is NOT blue which indicates that the temperature has not been too cold for HB, DPT, DT, Td, Hib or tetanus toxoid vaccines.

The indicator has burst and has stained the background 'BLUE'. This shows that the temperature has been below 0°C and there is a strong possibility that the HB, DPT, DT, Td, Hib or tetanus toxoid vaccines have been frozen.

If you suspect that these vaccines have been frozen follow the instructions below...

- Select some vials you think may have been frozen
- Select another vial of the same type of vaccine that you know for sure **was not** frozen
- Perform the **Shake test** as described to confirm or to rule out whether the vaccine being tested was frozen or not.

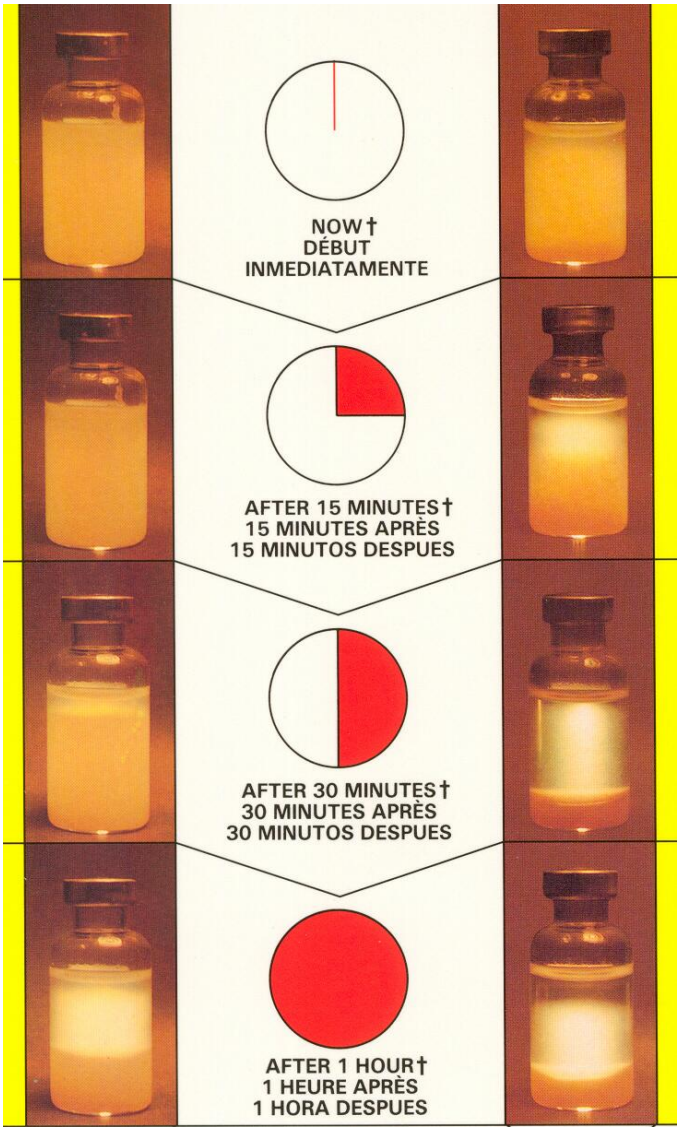
The Shake Test

(For vaccines which are sensitive to freezing DPT, TT, DT, Td, HB, Hib)

Compare the vaccine that you suspect has been frozen and thawed, with vaccine from the same manufacturer that you are sure was never frozen.

- Shake the containers of vaccine
- Inspect the contents carefully
- Leave the vaccines to stand side by side for 15-30 minutes for the sediment to settle
- Inspect the contents carefully again
- Always compare vials from the same manufacturer
- After some experience you should be able to recognise a frozen vial of vaccine in much less than 1 hour.

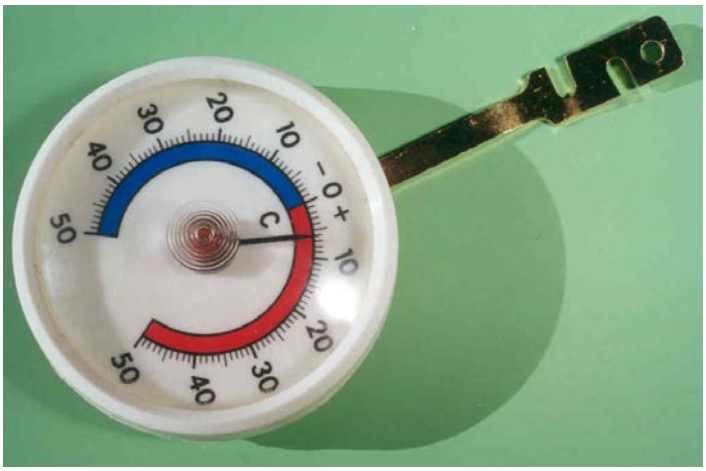
Fig. 13 Shake test



4.5 Types of Vaccine Thermometers

Strip (Crystal) Thermometer

Dial type Thermometer



Bar type Thermometer

Sensor type Thermometer

4.6 The Vaccine Vial Monitor

The Vaccine Vial Monitor (VVM) is one of the most significant developments in the history of cold chain technology. Applied directly to a vaccine vial by the vaccine manufacturer, it enables the health worker to verify at the time of use **whether each vaccine is in useable condition and/or has NOT lost its potency and efficacy due to temperature abuse.**

Vaccine itself exhibits no visible change with heat exposure. Prior to the development of the vaccine vial monitor, there was no way for the health worker to see if a vaccine had been properly refrigerated. Now, with the vaccine vial monitor, the health worker can easily see if a vial has had too much heat exposure and thus avoid giving heat-damaged vaccines to patients.

WHO, UNICEF and manufacturers of OPV decided in a meeting in Oct'94 that all vials of oral polio vaccine which meet WHO standards shall be fitted with vaccine vial monitors as of 1st January 1996.

The benefits of using vaccine vial monitors include:

- The ability to keep opened vials of polio vaccine until fresh supplies arrive
- A decrease of at least 30% in vaccine wastage rates
- The flexibility to take vaccine "beyond the cold chain" where it is necessary in reaching difficult locations and, above all
- It gives the health worker confidence that he/she is administering vaccine unharmed by exposure to heat.

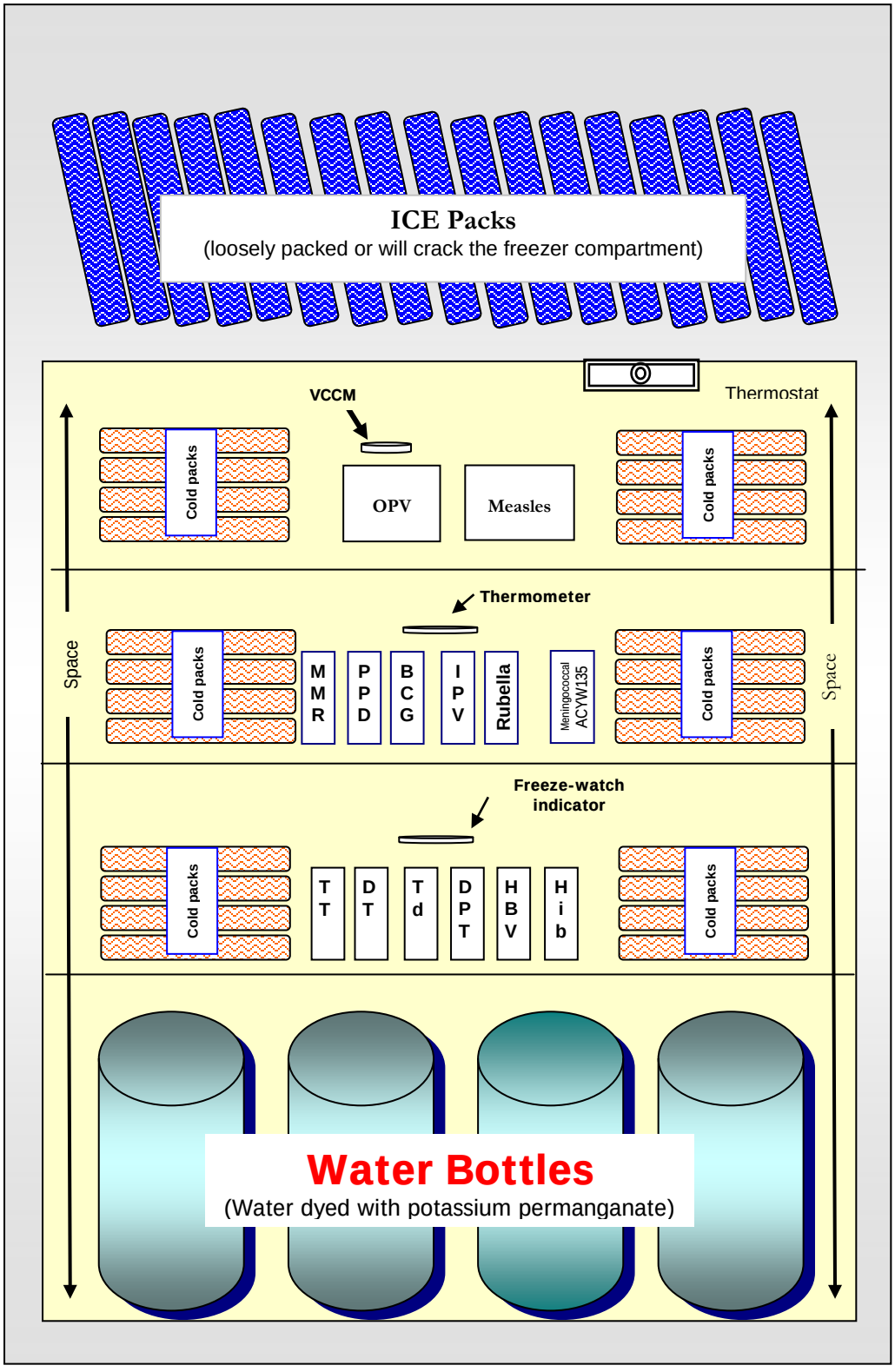
<u>Note:</u> Future shipments of all vaccines will contain individual vaccine vial monitors.

Fig 15: Vaccine Vial Monitor

Fig. 16

Vaccine Storage at EPI Unit

(Hospitals, Health Centres, Private Clinics and CDC)



Vaccine Storage Precautions at the EPI Unit

Who is responsible for the cold chain?

- Many staff members will use the vaccine refrigerator, but, **ONE** staff member must have overall responsible for it.
- The MOIC must nominate one staff member, by name, to be in charge of the vaccine refrigerator.

Prepare your vaccine refrigerator

- By removing all door-shelves, vegetable drawers, glass shelves etc. (Fig.16)
- No water bottles must be kept in the door.
- These items will be on the inventory of your hospital or health centre so please keep them safely in a cardboard box in your store room.

Vaccine storage time…

- At static unit or sub-stores level: store vaccines for a maximum of FOUR WEEKS.
- Regional stores level: store vaccines for a maximum of THREE MONTHS depending on vaccine storage capacity.

Fill freezer compartment with ice packs….

- To "store" cold i.e. To stabilise the refrigerator temperature and thus to increase the time that the refrigerator will maintain a safe temperature if the electricity or gas fails.
- To protect vaccines in an emergency i.e. To store the vaccines in a vaccine carrier (immunization unit) or cold box (regional store)
- To protect vaccines in transit e.g. for outreach teams

Control the temperature

- By using the Thermostat to keep the temperature between +2 to +8°C at ALL times.

Use your vaccine refrigerator properly…

- Use for vaccines only.
- Other drugs, etc. should be kept in another refrigerator
- Do not even think of keeping cold drinks or food in your vaccine refrigerator!

Monitor the temperature

- By placing the thermometer within the vaccines box.
- By placing Vaccine Monitors with the vaccines.
- By Placing the freeze-watch indicator with in the vaccines box.

What to do if the electricity or gas fails?

- If the power is cut for more than TWO HOURS you should remove all the vaccines AND cold chain monitors from the refrigerator and put them in your vaccine carrier or in a vaccine cold box; along with the appropriate ice packs and a vaccine thermometer.
- You can keep vaccines in a vaccine carrier for up to **24** hours or in a vaccine cold box for **3 to 5** days.

Record the temperature

- Use the new "Cold Chain Refrigerator Graph" (see fig.10 & 11) to plot the temperature twice a day.
- Plot the temperature at the (B)egining of the immunization session and at the (E)nd of the session.
- If you have two sessions per day, for example a morning and afternoon session, plot the temperature at the (B)egining of the first session and at the (E)nd of the second session.
- Keep these temperature records in a file for 2 years.

Vaccine Storage Precautions at the EPI Unit

Cold Chain failure…

- If the Cold Chain fails, or if you have any reason, to suspect it may have failed, you should not use the affected vaccines. Report the problem to your regional supervisors, and DSDC, and order more vaccines immediately.
- **There is NO shame or blame attached to reporting cold chain failure (although you should, obviously do your best to avoid it).**
- **Staff will only be blamed if they attempt to hide, or fail to report, cold chain failure; if in doubt… report it.**

Protect the vaccines from freezing…

- By keeping vaccines an arms width away from the evaporator plate. If vaccines touch the evaporator plate they will freeze and this will damage the vaccines, especially HBV, DPT,DT, Td, Hib and TT.

Stabilize the refrigerator temperature

- By keeping the door closed as much as possible. Cold air drops out of the refrigerator each time you open the door.
- By leaving space inside refrigerator for air to circulate; do this by keeping your vaccines, cold packs and water bottles one-hands-width from sides and back of your refrigerator
- If you have a small amount of vaccine (i.e. most health centres & smaller hospitals) then put extra cold packs/water bottles in fridge to help stabilise the temperature
- Please note that the purpose of the "extra cold packs" is to "store cold"; if you have a lot of vaccines in your refrigerator they will "store cold" and (providing the air can circulate) you have achieved the same aim.

Frozen DPT, TT, DT, Td, Hib or HBV ?

- Freezing destroys DPT, TT, DT, Td, HBV & Hib vaccine. It is a complete waste of every ones time to immunize with vaccine which has been destroyed.
- Because the visible results of freezing these vaccines varies from batch to batch you should / freeze one vial of any new batch of these vaccines you receive (we only get 2 or 3 new batches of each vaccine per year; you are NOT supplied with a new batch every month)
- Allow the frozen vial to thaw, MARK IT CAREFULLY (so that you don't use it by mistake) and use it as a sample to compare with all other vials of this batch of vaccine.
- Learn to tell the difference between vials of DPT / DT / TT/ Td / HBV / Hib which have been frozen and those which have not. The test to detect frozen vials is called **"the shake test"**; the EPI supervisors or your knowledgeable colleagues will tell you how to perform the test

Chapter

5

The Recording System

5.1 Introduction

A system for recording immunisation in the static units was brought into operation in MoH institutions from 1st August 1986. With the inclusion of new vaccines in the schedule the Child Health Register (MR-374) and Child Health Card (MR-224) have been modified from time to time and are periodically updated whenever required.

The recording system requires detailed supervision and meticulous paper work. The components of the recording system are elaborated below.

5.2 System Components

5.2.1 Child Health Register (MR – 374)

Each child should be registered in only one MR-374 Register in the country. This **"Master Register"** would normally be in the Hospitals/EHC./Health Centres unit closest to the place where the child lives and/or where the child will normally be brought for routine immunisation. This institution is known as the child's **"Parent Institution"**. The Parent Institution is responsible for ensuring that the children residing in their catchments area are fully immunised. Postnatal staff must ask a child's mother the location of her nearest health institution in order to ascertain the child's Parent Institution.

> ***Note:*** *normally, children should be registered in the Master Register in the month they were born e.g. all children born in August 95 would be registered together under that month & year. Regarding children born at home or outside Oman; these children should be registered under the month* they *were born. Few pages should be left blank at the end of the every month to register such children.*

5.2.2 Child Health Card (the pink card) MR-224

5.2.2 Child's Registration Number

The child's registration number also known as MR-374 number is made up of 3 parts: (See Annexure)

Note: *Registration Number should always be allocated by the child's parent institution and* ***Not*** *by the institution where the child was delivered, unless that is the child's parent institution as well e.g. children born at Khoula hospital but residing at Seeb should be given their MR-374 number at Seeb Health Centre which represents child's parent institution.*

5.3 Transfer of Responsibility

Children who are not residing in the catchments area of parent institution should not be entered in its Master Register. Instead the responsibility for that child should be transferred to their Parent Institution. Therefore, for example, a child born in *Tanam* Hospital, but living near *Dhank* Health Centre (HC) would not be registered in the *Tanam* Hospital Master Register, but in the *Dhank* HC Master Register. This Transfer of Responsibility for the child (children) will be carried out at the end of every week by despatching the **duplicate white part of the child health card duly filled** to the parent institution. These "transferred children" should then be entered into their Parent Institution Master Register under the month & year they were born. All static units should leave 2 to 3 blank pages at the end of each month entries so that the space is available to register children transferred-in from other institutions.

Write the name of the child's "Parent Institution" in his Child Health Card: to make it easy to tell which is child's Parent Institution. The name of the institution should be written on the child's health card when it is issued. For example, a baby girl born in *Khoula* Hospital whose parents live in *Suwaiq* area would have *"Suwaiq EHC"* written in her child health card.

5.3.1 Transferred in & Out

Sometimes the family moves out of the catchment area of the parent institution where the child was registered. In such situation the previous MR-374 number should be cancelled and a new number should be issued by the parent institution as if it's a new registration. For example a child was registered in *Seeb* health centre's master register and the family moved out to *Mutrah*. The old MR-374 number issued by *Seeb HC* would be replaced with a new number based on the next available number in the master register of *Mutrah HC* under the month and year of birth.

ALL Parent Institutions must register the child and issue the child health card as soon as the white copy of the MR-224 is received.

At times the mother would visit a health facility before the white copy was received. It is emphasized that NOT receiving the white copy of the card (due to reasons, such as postal delay) should not be considered a valid

reason for NOT registering the child. After ensuring the place of residence and birth details the child MUST be registered and issued the MR-224 number.

5.3.1 Hospitals without Master Register M-374

In some of the secondary/tertiary referral Hospitals deliveries are conducted but they do not keep the master register (MR-374). Such institutions do not represent a parent institution of that child for a certain catchment area. However these institutions are obliged to comply on the following points. These responsibilities should be carried out by a staff nurse specifically assigned to look after EPI.

- Issue the child health card M-224
- Record the birth vaccinations on MR-224
- Write the ANC number both on MR-224 card and the birth register
- Transfer mother's TT card from the ANC card to the child health card.
- Write the complete address including telephone number, village & Wilayat.
- Write the name of the parent institution of the child based on the place of residence.

5.4 EPI Feedback

Children who go to "other" institutions: if at any time a child is brought to any MoH institution which is not his/her Parent Institution, for any reason, and is screened and found to be due for next dose, then the EPI staff nurse must ensure that **he/she is immunised and the dose given should be entered in the child health card.**

'NO' OPPORTUNITY OF IMMUNIZING A CHILD MUST EVER BE LOST.

The details of the child and the past doses given should be written on an **"EPI Feedback Form M-246"** immediately and the copy of the form should be sent to the child's Parent Institution as soon as possible. The Parent Institute must then update its Master Register.

For example consider a five months old child from the *Ras Al Hadd* village (*Sur* Wilayat) was brought to *Sur* Hospital for some minor ailment. After screening in the OPD the EPI staff nurse finds that the second dose of DPT/OPV is due. She would immunise the child and then send details of the child and the vaccines given to *Ras Al Hadd* HC through Ministry post. The EPI staff nurse in *Ras Al Hadd* HC after receiving the feedback must then update the immunization records of that child in the master register.

Note: *the institution giving an immunisation dose, should report that dose along with all the other doses given that month on the normal Monthly Report Form. Thus continuing with the example above, Sur Hospital should report immunising this child, NOT Ras Al Hadd HC.*

5.5 Children Born At Home

It is estimated that less than 10% of all Omani children are born at home. However ALL of these children must be registered in the Master Register at their Parent Institution. If they are not registered then the chance of ensuring that they are fully immunised may be lost forever. All health workers should be aware of their responsibility to ensure that the names and other details of these children are entered in the Master Register.

As with so many aspects of EPI, community involvement is of vital importance here. Every attempt should be made to involve the community support group members to report the names and addresses of any babies born at home directly to the static unit.

Note: The Director General of Health Services in the Region or the MOIC should ensure that a child born at home has been issued a child health card before issuing a Birth Certificate.

5.6 EPI Defaulters

Once a child is registered in the Master Register in his Parent Institution, it will be a simple matter to see that he/she **progresses towards full immunisation on time.** For example, all the children registered in the month of January would be due for their next doses in February/March. They would be considered as EPI defaulters if they are not immunised **within one month from the due date**. Defaulters are to be retrieved by a combination of passive and active means.

5.6.1 Defaulter Retrieval

As soon as a child is known to be an EPI defaulter the Parent Institution should take steps to retrieve that child as follows:

- **Passive Defaulter Retrieval**: The Parent Institution attempts to retrieve the child through its own resources i.e. the EPI nurse would send messages directly to the family through the health workers (from the village), the local Sheikh, Community Support groups and the school teachers or anyone else who has influence in the community. This is community's involvement and has been shown to work in most areas. A Parent Institution would normally begin passive defaulter retrieval after the child has not come for immunisation within **1 to 2 weeks** from the due date.
- **Active Defaulter Retrieval**: once a child has not come for immunisation within **4 weeks** from the due date the EPI staff nurse should pass the responsibility for retrieving the defaulter to the nearest EPI Outreach Team. Defaulter Retrieval by EPI Outreach Teams is described later.

5.7 EPI Reporting

The following EPI reporting forms have been introduced since August 1990

(annexure):

5.7.1 EPI - Feedback Form

- **Purpose**: to inform a child's Parent Institution that one (or more) of their children have been immunised in another place so that they can update their Master Register.
- **Used by:** any static unit or outreach team
- **Sent to:** the Parent Institution as soon as possible by Ministry post.

5.7.2 EPI - Defaulter Retrieval Form

- **Purpose:** to inform a PHS/Outreach team that certain children are overdue for their next immunisation dose and are to be located and immunised as soon as possible.
- **Used by:** any PHS and/or Outreach team
- **Filled-out by:** EPI Static unit/Outreach team staff
- **Returned to:** the parent institution of the defaulting children before the end of the month or earlier (to update their Master Register).

5.7.3 EPI - Monthly Report

A monthly report form is to be completed by all units involved in EPI and sent to the DSDC through the Regional Directorate by **not later than 10th of the following month.** The form serves following purposes:

- Self assessment of the immunisation coverage of children for the institution's catchment area
- Summary of vaccine doses given to children in the reporting month.
- Summary of Tetanus Toxoid doses given in the reporting month
- Information on the number of vials used (for vaccine procurement and monitoring vaccine wastage)
- Surveillance of Vaccine preventable diseases (VPD)
- Monitoring of adverse events following immunisation

Note: All units must ensure that they report only those immunisations that are actually administered by them. They must NEVER report immunisation carried out by another unit.

5.8 Vaccine Stock Form & Forms for Record of Cleaning & Maintenance of Cold Chain Equipment

These forms are maintained by the in-charge staff of RVS, sub-RVS & static units according to the guidelines (See Annexure).

Chapter

6

The Outreach Strategy

6.1 Introduction

The EPI outreach immunization teams have made a major contribution towards the high immunisation coverage of the target children by covering the defaulters. These teams have been functional in specific problem areas identified in some administrative units. Routine procedures followed for the defaulter retrieval would not be applicable essentially due to absence of communication. This chapter of the manual describes the outreach strategy; a combination of defaulter retrieval procedures and visiting inaccessible villages.

6.2 Defaulter Retrieval

6.2.1 Detection & Active/Passive Defaulter Retrieval

Described in the Chapter 5.

6.2.2 The Defaulter Retrieval Procedure

MOIC of the Health Institution would be responsible to arrange to collect the names and addresses of the EPI defaulters from the local EPI static unit. Following standard procedures should be brought into operation by the Outreach Team.

- **Record confirmation:** Counter check the child's immunisation records in the MR-374 as well as duplicate white card to confirm the status.
- **Locate:** Find the child using the names and addresses written on the Defaulter Retrieval Form.
- **Explain:** Inform the parents that their child is overdue for his/her next dose and that it is important for the child to receive vaccines according to schedule for the full benefit.
- **Immunize:** Give the child the appropriate immunisation dose.
- **Educate:** Remind the parents of the importance of having their child

immunized and the diseases that are prevented and stress that they should bring their child to the Parent Institution when the next dose is due (write the due date in pencil on the card).

- **Report:** fill in the "action taken" section of Defaulter Retrieval Form (M-246) and make sure that the Parent Institution Master Register is amended with the dose given.

Procedures if the child cannot be found on the available address

If after a thorough search a child cannot be found the following procedures should be adopted:

- **Visit the Sheikh:** and ask his advice on ways and means of locating the child.
- **Report and discuss**: write 'not found' and the date in the "action taken" section of Defaulter Retrieval Form and then discuss the possible reasons for this with the static unit e.g. was the address not sufficient, etc and **follow-up**.

Procedure if the child is found to be already immunised

If the child has been immunised by the time he/she is located by the Outreach team, the team should:

- **Congratulate:** the parents for getting their child immunised and politely ask them to try to bring their child to the static unit on time in future.
- **Report and Discuss:** write "already immunised" and the date in the "action taken" section of Defaulter Retrieval Form and then discuss the possible reasons for this with the static unit e.g. did the outreach team started the action "too early" etc.
- Update the MR-374 Register by checking the defaulter retrieval form.

6.3 Procedure for Inaccessible Population

- **Selection:** the following procedures should be followed to mark the "Inaccessible areas/distant villages" in the Region.
- **Consultation:** the selection should be made in consultation with the MOIC of the static unit(s), and Regional MCH Committee.
- **Criteria:** the question to be asked is "Are the inhabitants of a village so far or inaccessible from a health facility that they rarely if ever visit the facility and would be unlikely to do so for anything that was NOT a clear emergency?" (i.e. not just to immunise their child)

  Note: *It is impossible to lay down a hard and fast rule saying exactly how far from a MoH institution a distant village would be because an inaccessible village in Musandam may be only 5 kilometres away, across a harsh terrain, whereas a distant village in Jalaan* ***might be*** *over 20 kilometres away.*

- **Planning a visit to a Distant Village:** PHS/Outreach Teams should not visit distant villages randomly. Visits must be rather planned and the community must be informed in advance. **Community involvement** can be achieved by liaison with the local Wali and Sheikhs who should be requested to arrange for ALL children under 6 years to be gathered at the central location of the village on a mutually convenient day. If the community can be mobilised in this way then it is not necessary to carry out house-to-house visits but instead use the age old "collection point" method.

  Note: *Unless it is ensured that ALL eligible children can gather at one location and the community would take its responsibility then only the house-to-house method may be abandoned.*

- **Procedure for "new children":** whenever an outreach team finds a "new child", that is a child under 2 years of age who has not been immunised before, they must ensure that they report the child's full details to the parent institution so that the child can be properly registered and then followed to full immunisation in the way described.

- **Supervision and monitoring:** The defaulter retrieval activities described above would only be successful if the teams are adequately supervised. The Director of Health Services of the Wilayat must therefore monitor and supervise these activities with firmness and sympathy. This include:
  - **Planning:** Help the Outreach team to plan the programme so that they achieve an optimum balance between defaulter retrieval activities with the visits to the distant villages.
  - **Community involvement:** Accompany the Outreach team when they visit the Wali and Sheikhs.
  - **Supervision in the institution:** The EPI staff nurse should ensure that the Outreach team leaves in time with the list of defaulters. Ensure that the team takes the required vaccines and equipment with them. Ensure that the team fills out various reports correctly.
  - **Supervision in the field**: Accompany the outreach team to the field at least once every month in order to see that all aspects of their work are in accordance with this manual and that their cold chain and immunization techniques are correct.

- **Outreach Teams' Productivity:** Defaulter retrieval and visiting distant villages are resource intensive activities. Teams spend a lot of time in travel to reach distant villages and searching for defaulters. It is inevitable that only few doses are administered in a day. This is perfectly acceptable and should not be criticised **as long as** the teams are finding all the defaulters in the area.

Chapter

7

The Immunization Session

All Hospitals, Health Centres and Public Health sections who are responsible for conducting immunisation sessions will follow the Standard Operating Procedures mentioned below.

7.1 Information to Mother

- Explain to mother which vaccine dose(s) you are offering to her child and what disease the vaccine(s) would prevent.
- Ensure that no mother leaves any immunisation session without a clear idea of exactly what disease(s) her child has just been protected against.
- Explain to the mother about the normal post-immunisation reactions; e.g. a fever after DPT, or a fever and rash after Measles.
- Provide the mother with the due date of her child's next dose (write the date on the child health card in pencil in the appropriate place) and politely stress to the mother the importance of bringing her child back on or around the due date.

7.2 Maintaining the cold chain during session

- Vaccines for use during an immunisation session should be kept in a **vaccine carrier** and not in a metal tray.
- Do NOT put frozen ice packs in the vaccine carrier directly. Keep the packs outside the freezer for 10-15 minutes before placing them in the vaccine carrier. This procedure would ensure that the vaccines like DPT, TT, DT, Td, Hib & HBV are not frozen during the session.
- A thermometer kept with the "in use" vaccines helps to monitor vaccine temperature during the session.

Arrangement of Ice Packs in the Vaccine Carrier

Placing the Vaccines in the Carrier (foam insert)

7.3 Immunisation Session

- **Open a vial of vaccine for even a SINGLE child** to immunise**.** Vaccines are cheap, children's lives are precious. Write the date and the time when you opened the vial.
- **Do not use spirit or alcohol** to clean the skin at the injection site or the vial cap. The alcohol can kill the live vaccines (if the mother insists you to clean the injection site then use clean cotton wool only). Explain politely to the mother that it is no longer considered necessary to clean the injection site.
- **Contaminating the vaccine:** Never insert a needle through the rubber CAP of the vaccine vial and then leave it in place to allow you to draw the vaccine throughout the immunisation session. Contaminated air can pass down the needle and damage the vaccine. **Also never re-inject the excess withdrawn vaccine back into the vial to avoid contamination.**
- **Use the same syringe & needle to draw & administer the vaccine:** It is unnecessary and a waste of resources to use one needle to draw the vaccine and another (new) needle to inject the child. The quality of modern stainless steel needles will not be affected by piercing the cap. Therefore the staff should use the same syringe and needle to draw and also to administer the vaccine.

7.4 WHO Policy on use of Opened Vaccine Vials

Sufficient data has been collected by WHO on the safety and potency of EPI recommended vaccines to endorse a change in the global policy on the use of opened vials of vaccine. The revised policy has the potential to reduce vaccine wastage rates by 30%, resulting in annual savings worldwide of US $ 40 million in vaccine costs.

A. Revised WHO/EPI policy

The revised policy applies only to vaccines which:

- Meet WHO requirements for potency and temperature stability
- Are packaged according to ISO standards
- Contain an appropriate concentration of preservative, such as thiomersal (for injectable vaccines only)

Note: Vaccines supplied by UNICEF also meet these requirements

Opened vials of Measles, MMR, & BCG vaccines must be discarded at the end of each immunisation session (8 hours)

An opened vial must be discarded immediately if any of the following conditions apply…

- If sterile procedures were not fully observed OR
- If there is a suspicion that the opened vial has been contaminated, OR
- If there is visible evidence of contamination, such as a change in appearance, floating particles, etc.
-

B. Rationale for changing EPI policy on opened vaccine vials

Two issues dictate the EPI policy on the use of opened vaccine vials:

- The **potency** of the vaccine and
- The **safety** of administration

Since the original policy statement was issued, research has been conducted to determine how these two factors are affected over time.

Potency:

The potency of vaccine over time is determined primarily by…

- The heat stability of that particular vaccine and
- Whether or not the vaccine was reconstituted

The potency of OPV, TT, DTP, DT, Td and hepatitis B is a function of heat stability and opened vials of these vaccines remain potent as long as they are stored under appropriate cold chain conditions (+2° to +8°C).

Safety: The safety of an opened vial of vaccine is primarily depends on…

- The risk of contamination with a pathogenic organism and
- The bacteriostatic or viricidal effect of preservatives in the vaccine

7.5 MoH Revised Policy Opened Vaccine Vials

- BCG, Measles & MMR are reconstituted vaccines and hence must be discarded at the end of the immunisation session (8 hours).
- MoH revised policy recommends that OPV can be used as long as the VVM does not show any colour changes.
- DPT, DT, TT, Td, Hib and Hepatitis B can be kept up to 7 days (1 week) subject to the conditions stated below:
  - The expiry date has not passed,
  - The vaccines are stored under appropriate cold chain conditions (+2° to +8° Celsius) **and**
  - Opened vials of vaccine which have been taken out of the health institution for immunisation activities (e.g. outreach, NIDs) are discarded at the end of the day.
- Always write the date & time on the vial after opening it.

Potential benefit of the above revised policy is that wastage would be cut down with NO compromise on the safety and the potency.

7.6 Disposal of Used Vials

- It is unwise to dispose off used vials of vaccine in an unsafe manner.
- ALL immunisation used vials of vaccine must be disposed-off in sealed containers.
- These containers MUST NOT be thrown into the Municipality drums but should be handed over to the Municipality worker personally or to be incinerated on site if facilities are available.

7.7 Golden Rules

- Look directly into the mother's eyes.
- Smile at the mother and child.
- Congratulate the mother for bringing her child for immunisation.

Chapter

8

The Injection Safety

8.1 Introduction

There are three levels of definitions for a safe injection. The first level is an ideal, reference definition. The second level represents international best practices that are a translation of the reference definition into an explicit list of critical steps for which best practices are recommended on the basis of (a) best available evidence or (b) expert consensus in the absence of evidence. The third level is the adaptation of international best practices into a national standard taking into account operational constraints in the field.

- **A Safe injection** is that which does not harm the recipient, does not expose the provider to any avoidable risk, and does not result in any waste that is dangerous for other people.
- **National standards:** The injection safety should target the following three levels:

    1. The safety of the injection recipient
    2. The safety of the health care worker
    3. The safety of the community

8.2 Type of Equipment

- **Single use syringes and needles (disposable):** Single-use syringes and needles are appropriate for all types of immunization strategies, including use in static clinics and in outreach or during special campaigns. A sterile packed syringe and a sterile packed needle must be used for each injection and they must be disposed off immediately after use.
- **Autodestruct (auto-disable) or AD** syringes are designed so that it is **impossible** to use them more than once. Consequently they present the lowest risk of person-to-person transmission of blood-borne infections. These are

preferred for administering vaccines, particularly in mass immunization programmes. The MoH is contemplating to introduce AD syringes for EPI in near future.

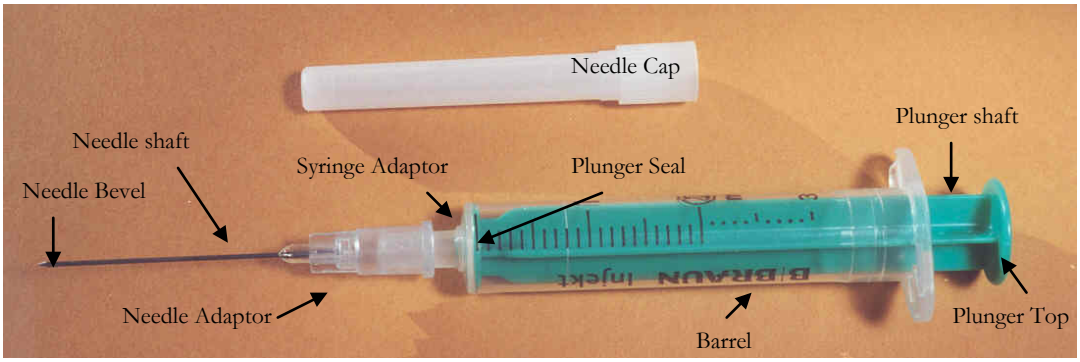
Table
Sizes of syringes and needles

Use	Syringe size	Needle size
BCG (for ID injections)	1 ml	Single-use (26 gauge)
All other EPI vaccines (for IM or SC injections)	2 ml	Single-use (23 gauge)
Reconstitution	5 ml	(22 gauge)

Parts of needle and syringe

It is important to know that parts of the needle and the syringe in order to handle the equipment safely.

2ml Syringe



AD Syringe

8.2 Handling syringes and needles safely

The following procedures and rules should be adopted:

Do not touch EVER:

- The shaft of the needle
- The bevel of the needle
- The adaptor of the needle
- The adaptor of the syringe
- The plunger seal of the syringe
- The plunger shaft of the syringe

If you touch any of these parts accidentally, discard the syringe and needle.

You may however touch:

- The barrel
- The plunger top

All syringes and needles must be safely disposed off after single use.

8.3 Procedures for disposing of injection equipment

Before disposal, syringes and needles should be placed in a puncture-proof container. Special boxes for collection and destruction by burning may be purchased. These are water proof and tamper-proof and needles cannot pierce them.

Alternatively, you may use containers made of thick plastic or metal cans, for collecting syringes and needles and transporting them to an incinerator or other site where they can be burned.

Follow these steps to dispose off injection equipment safely:

- Place disposable syringes and needles after use directly in the disposal box. To avoid needle-stick injuries, **DO NOT attempt to recap the needle or to separate the syringe and needle.**
- Contaminated sharps should not be transferred from container to container.
- **When the box is full, dispose it by burning.** The disposal box should be destroyed by incineration as close as possible to the point of use and as soon after the immunization session as is practical. The compound in which incineration takes place must be secure. Auto-combustion incinerators, achieving temperatures above 800º C are preferred, although burning can also

be performed in other types of incinerator for instance in a pit, drum or constructed hearth.

- **Preventing injuries and infections.** You can reduce the risk of injuries and infections when handling injection equipment as follows:

1. Take care to prevent injuries when using and handling needles during and after finishing the injection procedure as well as during the disposal.
2. Do not recap used needles or do not remove used needles from syringes by hand.
3. Place used syringes and needles in puncture-proof containers for final disposal. Keep a container as close as possible to the place where you give injections but it should be away from the reach of children.
4. Immediately and thoroughly wash hands and other skin surfaces that have been contaminated with blood or other body fluids.

Safe Disposal Containers

Supervision & Evaluation

Systematic supervision and periodic evaluation of injection practices are vital to ensure safety. Supervisory visits should be made by the EPI focal point to each health centre at least twice in a year. A standardised checklist should be utilised that includes points on injection safety. An assessment of safe injection practices, injection equipment and the equipment supply system is included in the EPI programme review and evaluation activities performed by the National EPI supervisors. All injection-related adverse events should be routinely monitored regionally and nationally and investigated with a view of improving the safety of injections.

Chapter

9

The Quality and Auditing System

9.1 Introduction

Regular, supportive, firm, but sympathetic supervision is one of the most most important components of the successful EPI programme. On the the spot training or re-training is an integral part of such supervision.

During the early implementation of EPI, the national supervisors played a key role in ensuring uniform quality of the programme implementation in the country. Gradually after the decentralization began the regional component of supervision was strengthened. National training workshops as well as in-service training were conducted. Experienced health workers were nominated as the focal points for EPI in the regions

9.2 EPI Regional supervisors targets

- **Supervision**: Each supervision team must aim to supervise ALL units in their area of responsibility on a periodic basis. Weak units should be frequently supervised and re-trained as much as is necessary to solve their problems.
- **Training**: the supervisors have a responsibility to train or re-train as necessary, all personnel involved in EPI in their area.

9.3 Supervisory responsibilities

1. The EPI supervision teams must maintain the following records for their area:
   - **List of units:** All static units and outreach teams and their areas of responsibility e.g. Wilayat/villages/static units served by each Outreach team.
   - **List of personnel:** In each unit/team.
   - **List of doctors who supervise EPI**: i.e. the doctors who, in institutions with more than 2 doctors, have been nominated to supervise their EPI

activities.

2. **Supervise the Cold Chain:** to ensure the integrity of the Cold chain particularly in their area.

Table

The Regional & Sub-regional Vaccine Stores in Oman, 2002

Region	Regional Vaccine Store	Sub-Regional Vaccine Store	Responsibility
Muscat	Darseit	Pharmacist	
Dhofar	SQ Hospital, Salalah		
North Batinah	Sohar EHC	Shinas HC Suwaiq HC Khaburah HC Saham Hospital	
South Batinah	Rustaq Hospital		
Dakhliyah	Nizwa PHS	Sumail Hospital Bahla Hospital	
Dhahira	Tanam Hospital	Buraimi Hospital	
North Sharqiyah	Ibra Hospital	Sinaw Hospital	
South Sharqiyah	BBB Hassan PHS	Sur Hospital BBB Ali Hospital	
Musandam	Khasab Hospital	Diba Hospital	
Al Wustah	Haima Hospital		

Chapter

10

The School Immunizations

10.1 Introduction

School education in Oman has a high priority and is universally and socially accepted. Almost the entire population of children between the ages of 6 to 12 years attend the school and hence are accessible for immunization and follow-up.

Probably the most important part of the School Immunization Programme is the opportunity to immunize almost ALL girls in Oman. This opportunity must not be lost to sustain the elimination of neo-natal tetanus in Oman. **Every girl who leaves school MUST therefore be fully immunized with TT.**

10.2 Responsibilities

- Immunizations in schools should be carried out by the *School Health Visitor* (SHV) and doctors, but if there is no school health visitor for an area the programme must still be completed by the staff in the health facility within their school's catchment area.
- **Recording:** All school immunization should be recorded in the School Health Student Record. Additional details are available in the MoH manual on School Health.

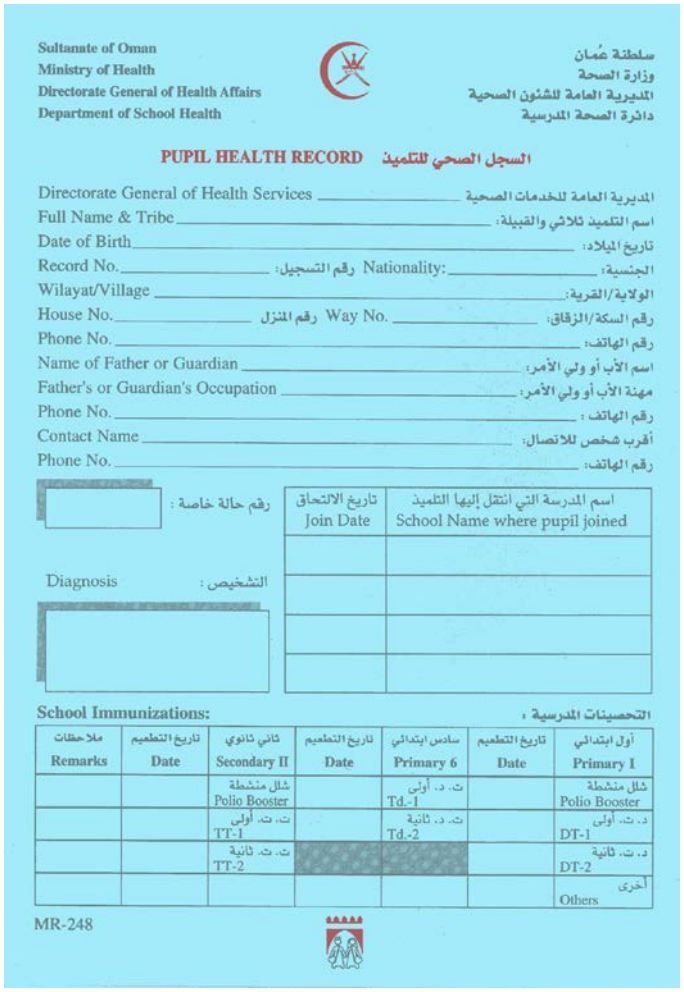
10.3 School Immunization Schedule

See page 9 for details.

Note: Those students who present without any documentary evidence of primary immunization should be investigated thoroughly and the reasons for the same should be ascertained through interviewing the parents & family. This will give an opportunity to assess the immunization status of the mother & other siblings.

The School Health Student Record

Boys



Sultanate of Oman
Ministry of Health
Directorate General of Health Affairs
Department of School Health

سلطنة عُمان
وزارة الصحة
المديرية العامة للشئون الصحية
دائرة الصحة المدرسية

PUPIL HEALTH RECORD السجل الصحي للتلميذ

Directorate General of Health Services _____ المديرية العامة للخدمات الصحية
Full Name & Tribe _____ اسم التلميذ ثلاثي والقبيلة:
Date of Birth _____ تاريخ الميلاد:
Record No. _____ رقم التسجيل: Nationality: _____ الجنسية:
Wilayat/Village _____ الولاية/القرية:
House No. _____ رقم المنزل Way No. _____ رقم السكة/الزقاق:
Phone No. _____ رقم الهاتف:
Name of Father or Guardian _____ اسم الأب أو ولي الأمر:
Father's or Guardian's Occupation _____ مهنة الأب أو ولي الأمر:
Phone No. _____ رقم الهاتف :
Contact Name _____ أقرب شخص للاتصال:
Phone No. _____ رقم الهاتف:

رقم حالة خاصة :

اسم المدرسة التي انتقل إليها التلميذ School Name where pupil joined	تاريخ الالتحاق Join Date

Diagnosis التشخيص :

School Immunizations: التحصينات المدرسية :

ملاحظات Remarks	تاريخ التطعيم Date	ثاني ثانوي Secondary II	تاريخ التطعيم Date	سادس ابتدائي Primary 6	تاريخ التطعيم Date	أول ابتدائي Primary I
		شلل منشطة Polio Booster		ت. د. أولى Td.-1		شلل منشطة Polio Booster
		ت. ت. أولى TT-1		ت. د. ثانية Td.-2		د. ت. أولى DT-1
		ت. ت. ثانية TT-2				د. ت. ثانية DT-2
						أخرى Others

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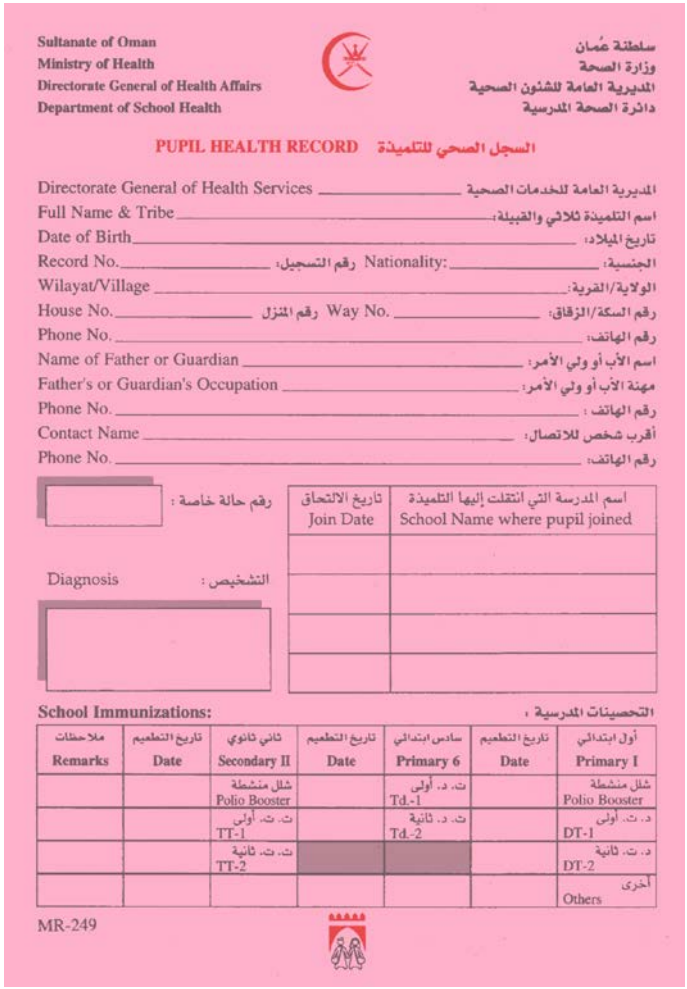
Girls



Sultanate of Oman
Ministry of Health
Directorate General of Health Affairs
Department of School Health

سلطنة عُمان
وزارة الصحة
المديرية العامة للشئون الصحية
دائرة الصحة المدرسية

PUPIL HEALTH RECORD السجل الصحي للتلميذة

Directorate General of Health Services _____ المديرية العامة للخدمات الصحية
Full Name & Tribe _____ اسم التلميذة ثلاثي والقبيلة:
Date of Birth _____ تاريخ الميلاد:
Record No. _____ رقم التسجيل: Nationality: _____ الجنسية:
Wilayat/Village _____ الولاية/القرية:
House No. _____ رقم المنزل Way No. _____ رقم السكة/الزقاق:
Phone No. _____ رقم الهاتف:
Name of Father or Guardian _____ اسم الأب أو ولي الأمر:
Father's or Guardian's Occupation _____ مهنة الأب أو ولي الأمر:
Phone No. _____ رقم الهاتف :
Contact Name _____ أقرب شخص للاتصال:
Phone No. _____ رقم الهاتف:

رقم حالة خاصة :

اسم المدرسة التي انتقلت إليها التلميذة School Name where pupil joined	تاريخ الالتحاق Join Date

Diagnosis التشخيص :

School Immunizations: التحصينات المدرسية :

ملاحظات Remarks	تاريخ التطعيم Date	ثاني ثانوي Secondary II	تاريخ التطعيم Date	سادس ابتدائي Primary 6	تاريخ التطعيم Date	أول ابتدائي Primary I
		شلل منشطة Polio Booster		ت. د. أولى Td.-1		شلل منشطة Polio Booster
		ت. ت. أولى TT-1		ت. د. ثانية Td.-2		د. ت. أولى DT-1
		ت. ت. ثانية TT-2				د. ت. ثانية DT-2
						أخرى Others

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Chapter

11

Immunizations in Private Sector

11.1 Introduction

It is the policy of MoH to vaccinate all children under six years of age against the 10 vaccine preventable diseases, and to vaccinate all women of child bearing age with TT. Hence in conformity of the policy it is imperative that the private health establishments catering to a certain proportion of the population must also follow these guidelines.

In order to ensure that the policies are followed in the private sector, the Directorate General of Health Affairs (DGHA) would supply vaccines (except for HBV & MMR) to the existing vaccine qualified private clinics in the country provided certain prerequisites outlined below are satisfied.

11.2 Vaccine Qualified (VQ) Clinics

A VQ clinic would be liable to periodic supervision and audit by National EPI supervisors from DSDC. If a clinic fails to maintain the required standards it would be withdrawn from the VQ list and would automatically cease to be entitled to draw vaccines under the EPI programme.

- **EPI Schedule:** Clinics must understand the EPI Schedule as practiced in the Sultanate of Oman and must comply with it in respect of doses, dose interval and method of administration.
- **Cold Chain:** Clinics must equip themselves with and then adequately maintain the necessary refrigeration equipment required to ensure that the vaccines they have remain potent.
- **Recording:** Clinics must understand that once they embark on the immunization of a particular child they must follow-up that child to ensure that the child is fully immunized as per the MoH policy.

- **Reporting:** Clinics must make regular reports to EPI programme manager in DSDC on the progress of the immunization activities according to the laid down schedule.
- **The VQ clinics can administer other vaccines not included in the EPI schedule but licensed by MoH viz. Hepatitis A, Varicella, Influenza, Tetra/Penta etc.. These vaccines are available in private pharmacies.**
- **Examination:** In order to establish beyond any doubt that a private clinic is fully conversant with the EPI programme, the management of the Cold-Chain and the DSDC/EPI Recording and Reporting requirements (i.e. before a Private Clinic can be judged VQ), the MOIC of that clinic must pass an examination in all these subjects.

11.3 Recording & Reporting

- All private clinics must maintain an immunisation record register as per the format recommended by EPI/DSDC. This register must be kept updated and would be inspected during routine visits by the national EPI supervisors.
- Accurate and timely reporting is a major component of a satisfactory vaccination programme. For this reason VQ clinics must understand and comply with the following reporting schedule:
- **Monthly Vaccination and consumption summary:** to be completed each month and submitted to EPI/DSDC by not later than 10th of the following month. EPI monthly report form should be utilised for this purpose.
- **Feed back summary:** Details of immunisation given are to be filled out in the "Feed back form" and immediately dispatched to the parent institution for updating the MR-237 register.

11.4 Training

- It is the responsibility of Private Clinics to become VQ and not the responsibility of EPI/DSDC to qualify them. The MOIC of any private Clinic seeking VQ status must study and learn (and pass an examination in) the EPI, the Cold-Chain management procedures and the recording and reporting protocols.
- EPI/DSDC will be available to advise, assist or to clarify any points which are not clear in the above documents. However, such advice can only be given on an "as available basis" i.e. when the EPI/DSDC supervisors have time to spare from their responsibilities. In short, although EPI/DSDC will do its best to help Private Clinics whenever required. Private Clinics do not have the right to demand such services at a time of their own convenience.

11.5 Supervision & Audit

- EPI/DSDC has a responsibility to supervise and audit all immunization activities in the Sultanate of Oman.
- For this reason, and because the DGHA would be supplying vaccines to Private Clinics (under the terms of this Protocol), EPI/DSDC will exercise strict supervision over VQ Clinics.
- This supervision will take the form of unannounced spot checks whose aim would be to see that Private Clinics are following the terms of this Protocol.
- Any Private Clinic found in serious violation of the terms of this Protocol will be reported immediately to the Director General of Health Affairs of the Ministry of Health (HQ) with the recommendation that the Clinic's VQ status be withdrawn immediately.
- Any Private Clinic which loses its VQ status will have to return all unused vaccine stocks to EPI/DSDC and will lose its entitlement to draw free supplies of vaccines in the future.
- Applications for reinstatement of VQ status will be dealt with on a case by case basis and are liable to be given very rarely

Annex 1

Sultanate of Oman
Ministry of Health

Directorate General of Health Affairs
Dept. of Surveillance & Disease Control

AEFI Case Investigation Report

To **Department of Surveillance & Disease Control** **Directorate General of Health Affairs** ***Fax 601832***	**Institution:** **Region:** **Date:** ...../...../.....

1st Name:		2nd Name:	3rd Name:	Tribe:
DOB/Age:	Sex: M / F	Nationality:	OPD/IPD No.:	MR2 No.:
Wilayat:		Village:	Tel. No.:	House No.: Land Mark:

I. Name of the suspect vaccine:				No. of doses per vial:
Batch No. of vaccine:	Storage Temp.:	Mfd. by:	Mfd. Date: ...../...../.....	Exp. Date: ...../...../.....
Lot No. of diluent: (if relevant)		Mfd. by:	Mfd. Date: ...../...../.....	Exp. Date: ...../...../.....
Syringe used (company name):		Lot No.:	Mfd. place:	Exp. Date: ...../...../.....
Date of Injection: ...../...../.....		Time:	Site of Injection:	
Injection given by (name/designation):		Institution:	Admission: ☐ Yes ☐ No If yes, Date of admission: ..... / ..... /	
Time of reactions (onset of symptoms):		Time of recovery:	Outcome:	

II. Immunization History: *(Attach photocopy of child health card)*	III. Laboratory Findings (if relevant):	IV. Management:
V. Medical history: *H/O reactions to previous doses, drug allergies etc.*	VI. Event summary:	

VII. Symptoms of AEFI **(Check only the appropriate box)**

☐ **Injection-site abscess (requiring drainage):** ☐ Yes ☐ No

☐ **Lymphadenitis:** Suppurative lymphadenitis ☐ BCG-adenitis ≥ 1.5mm ☐

☐ **Local Adverse Reactions:**

- ☐ Pain, swelling and redness at the site of injection
- ☐ *Redness &/or swelling centred at the site of injection*
  AND one of the following:
  - ☐ Swelling beyond the nearest joint
  - ☐ Pain, redness and swelling of more than three days duration
  - ☐ Requires hospitalization

☐ **Systemic Adverse Reactions:**

Non-specific symptoms: *(e.g. fever above 39^0 C, malaise, headache, persistent screaming ..... etc)*

Specify: .....

☐ CNS adverse events:

☐ Acute paralysis	☐ Seizures (febrile or afebrile)
☐ Meningitis	☐ Encephalitis
☐ Encephalopathy	☐ Other (specify) .....

☐ Allergic Reactions:

☐ Generalized urticaria	☐ Toxic-shock syndrome
☐ Breathing difficulty	☐ Disseminated BCG-adenitis
☐ Anaphylactic shock	☐ Hypotension
☐ Acute hypersensitivity reaction *(anaphylactoid reaction)*	☐ Other (specify) .....

☐ **Other Adverse Reactions (Specify):** *e.g. Osteitis, Osteomylitis, Arthralgia etc*
.....

Investigated by (Name):	**Signature:**

Annex 2

Monitoring of Adverse Events Following Immunisation

List of Definitions

All of the following adverse events should be reported if temporally related to immunisation. Unless otherwise specified this includes all such events occurring within four weeks of a vaccine administration.

1. Local Adverse Events

A. Injection-site Abscess: Occurrence of a fluctuant or draining fluid-filled lesion at the site of injection with or without fever.

Bacterial: Existence of purulence, inflammatory signs, fever, positive Gram stain, positive culture, or finding of neutrophil predominance of content will support a bacterial site abscess, but the absence of some of these signs will not rule it out.

Sterile: There is no evidence of bacterial infection following investigation

B. Lymphadenitis (includes suppurative lymphadenitis)

Occurrence of either:

- At least one lymph node, 1.5 cm in size (one adult finger width) or larger; **OR**
- A draining sinus over a lymph node

Almost exclusively caused by BCG and then occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as the site of inoculation (mostly axillary).

C. Severe Local Reaction

Redness and/or swelling centred at the site of injection and one or more of the following:

- Swelling beyond the nearest joint
- Pain, redness and swelling of more than 3 days duration; OR
- Requires hospitalization

Local reactions of lesser intensity may occur commonly and are generally of little consequence. For monitoring purposes, priority should be given to severe local reactions as defined above.

2. Central Nervous System Adverse Events

Acute Paralysis

- **Vaccine-Associated Paralytic Poliomyelitis**

  Acute onset of flaccid paralysis within 4 to 30 days of receipt of oral poliovirus vaccine (OPV), or within 4 to 75 days after contact with a vaccine recipient, with neurological deficits remaining 60 days after the onset, or death.
- **Guillain-Barre Syndrome (GBS)**

Acute onset of rapidly progressive, ascending, symmetrical flaccid paralysis, without fever at onset of paralysis and with sensory loss. Cases are diagnosed by cerebrospinal fluid (CSF) investigation showing dissociation between cellular count and protein content. GBS occurring within 30 days after immunisation should be reported

Encephalopathy

Encephalopathy is an acute onset of major illness temporally linked with immunization and characterized by any two of the following three conditions:

- Seizures
- Severe alteration in level of consciousness lasting for one day or more; and
- Distinct change in behaviour lasting one day or more.

Cases occurring within 72 hours after vaccination should be reported.

Encephalitis

Encephalitis is characterized by the above mentioned symptoms and signs of cerebral inflammation and, in many cases, CSF pleocytosis and/or virus isolation. Any encephalitis occurring within 1 - 4 weeks following immunization should be reported

Meningitis

Acute onset of major illness with fever, neck stiffness/positive meningeal signs (Kernig, Brudzinski). Symptoms may be subtle and similar to those of encephalitis. CSF examination is the most important diagnostic measure: CSF pleocytosis and/or detection of microorganism (Gram stain or isolation).

Seizures

Seizures lasting from several minutes to more than 15 minutes and not accompanied by focal neurological signs or symptoms

- Febrile Seizures; OR
- Afebrile Seizures

3. Other Adverse Events

Allergic Reaction

Characterized by one or more of the following: 1) skin manifestations (e.g. hives, eczema); 2) wheezing; 3) facial or generalized oedema.

Anaphylactoid Reaction (acute hypersensitivity reaction)

Exaggerated acute reaction, occurring within 2 hours after immunization, characterized by one or more of the following:

- Wheezing and shortness of breath due to bronchospasm
- Laryngospasm/laryngeal oedema;
- One or more skin manifestations, e.g. hives, facial, or generalized oedema.

Anaphylactic Shock

Circulatory failure (e.g. alteration of the level of consciousness, low arterial blood pressure, weakness or absence of peripheral pulses, cold extremities secondary to reduced peripheral circulation, flushed face and increased perspiration) with or without bronchospasm and/or laryngospasm/laryngeal oedema leading to respiratory distress occurring immediately after immunization

Arthralgia

Joint pain usually including the small peripheral joints

Persistent: Joint pain lasting longer than 10 days.

Transient: Joint pain lasting up to approximately 10 days.

Disseminated BCG-itis

Disseminated infection occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of Mycobacterium bovis BCG strain.

Fever

- Fever**, mild:** Temperature 38.9°C (rectal)
- Fever, **high:** Temperature 39°C to 40.4°C (rectal)
- Fever, **extreme (hyperpyrexia):** Temperature higher than or equal to 40.5°C (rectal)
- **Fever, unspecified:** Temperature presumed to be high but not measured

Only high and extreme fever should be reported.

Hypotensive - Hyporesponsive Episode (shock collapse)

Sudden onset of paleness, decreased level or loss of responsiveness, decreased level or loss of muscles tone (occurring within 24 hours of vaccination). The episode is transient and self-limiting

Ostitis/Osteomyelitis

Inflammation of the bone either due to BCG immunisation (occurring within 8 to 16 months after immunisation) or caused by other bacterial infection.

Persistent Screaming

Inconsolable continuous crying lasting at least 3 hours accompanied by high-pitched screaming.

Sepsis

Acute onset of severe generalised illness due to bacterial infection and confirmed by positive blood culture.

Toxic-Shock Syndrome

Abrupt onset of fever, vomiting and watery diarrhoea within a few hours of immunization, often leading to death within 24-48 hours.

Any death of a vaccine recipient temporally linked (within 4 weeks) to immunization, where no other clear cause of death can be established, should be reported.

In addition any other severe and unusual events occurring within 4 weeks after immunization and not specified in the above description should be reported.

Annexure 3

Important Phone Numbers

2002

National EPI Program

Name of Supervisor	Designation	Telephone
Dr. Salah Al Awaidy	Programme Manager	Office: + (968) 601921, 607524 Res.: + (968) 545489 GSM:
Dr. Shyam Bawikar	Epidemiologist	Office: + (968) 601921, 607524 Res.: + (968) 683695 GSM: 9368327
Mr. Abraham	Pharmacist I/C Central Vaccine Stores, Darsait	Office: + (968) Pager:

National EPI Supervisor (Head Quarters)

Name of Supervisor	Regions	Office Telephone
Mr. Islam Al Balushi	South Batinah North Batinah, Muscat	Office: + (968) 607524
Mr. Bader Saif Al Rawahi	Dhofar, Dakhliyah Dhahira, Al Wustah, & Muscat	
Mr. Hussamuddin Nawar	South Sharqiyah, North Sharqiyah, Musandam, Muscat	

EPI Regional Supervisor (focal point)

Region	Name of Supervisor	Office Telephone
Muscat	Mr.	782110
Dhofar	Mr. Bakheet Ali Safrar	210130
North Batinah	Ms. Khadija Hassan Al Balushi	842545
South Batinah	Mr. Waleed Khamis Al Hadebi	875434
Dakhliyah	Mr. Nasserulla Khalaf Al Tobi	411159
Dhahirah	Mr. Said Nasser Al Kalbani	491870
North Sharqiyah	Mr. Dawood Dudin Al Balushi	470534
South Sharqiyah	Mr. Fisal Said Al Mekhini	444501
Musandam	Dr. Mohammed Al Ghobashy	830137
Al Wustah	Mr. Mahmood Salem Al Raqmi	436013

Annex 4